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TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 – RADIATION

PART 5 – Therapeutic Radiation Machines

5.1 Authority and Incorporation by Reference

5.1.1 Authority

A. This Part is promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-1.3-5.

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

C. The use of therapeutic radiation machines must be by, or under the supervision of, an Authorized Physician who meets the criteria established by § 5.3.3 of this Part.

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

1. If the research will be conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects (45 C.F.R. Part 46), the registrant must, before conducting research:

    a. Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

    b. Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject; or

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

    a. Apply for and receive approval of a specific amendment to its Agency registration; and

b. Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

c. Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

E. FDA, Other Federal and State Requirements. Nothing in this Part relieves the registrant from complying with applicable Agency, FDA, other Federal, and State requirements governing therapeutic radiation machines or auxiliary devices.

F. Electronic brachytherapy devices are subject to the requirements of § 5.8 of this Part and are exempt from the requirements of § 5.6 of this Part.

G. Any notifications, reports or correspondence required by this Part must be directed to the Agency using contact information specified in § 1.4 of this Subchapter.

5.1.2 Incorporation by Reference

A. These Regulations hereby adopt and incorporate the National Council on Radiation Protection and Measurements' (NCRP) Report 49 "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations.

B. These Regulations hereby adopt and incorporate the National Council on Radiation Protection and Measurements' (NCRP) Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations.

C. These Regulations hereby adopt and incorporate the National Council on Radiation Protection and Measurements' (NCRP) Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations.

D. These Regulations hereby adopt and incorporate the National Council on Radiation Protection and Measurements' (NCRP) Report 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities" (2006) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations.

5.2 Definitions

A. Whenever used in this Part, the following terms must be construed as follows:

1. “Absorbed dose" or "D” means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The units of absorbed dose is the gray (Gy). One gray (Gy) is the international system of units (SI) equivalent of one hundred (100) rads, which is equal to an absorbed dose of one (1) joule/kilogram.

2. “Absorbed dose rate” means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for electrically generated radiation producing devices.

3. “Act” means R.I. Gen. Laws Chapter 23-1.3, entitled "Radiation Control."

4. “Agency” means Rhode Island Radiation Control Agency (RCA), Center for Health Facilities Regulation – Radiation Control Program, Rhode Island Department of Health.

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

6. "Authorized physician" means a physician who is qualified to be named on an Agency therapeutic radiation machine registration by satisfying the requirements of § 5.3.3 of this Part.

7. “Barrier” (See "Protective barrier").

8. “Beam axis” means the axis of rotation of the beam limiting device.

9. “Beam-limiting device” means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

10. “Beam monitoring system” means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

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

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

13. “Changeable filters” means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

14. “Contact therapy system” means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five (5) centimeters.

15. “Conventional simulator” means any X-ray equipment designed to reproduce the geometric conditions of the radiation therapy equipment.

16. “Detector” (See "Radiation detector").

17. “Dose monitor unit" or "DMU” means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

18. “Dosimetry system” means an ion chamber and electrometer used as a dosimeter for measurement of clinical photon and electron beams with calibration coefficients determined either in air or in water and are traceable to a national primary standards dosimetry laboratory. Specialized dosimetry systems are available for detecting different radiation types.

19. “Electronic brachytherapy” means a method of radiation therapy where an electrically generated low-energy source of ionizing radiation is placed in or near the tumor or target tissue to deliver a therapeutic radiation dose.

20. “Electronic brachytherapy device” means the system used to produce and deliver therapeutic radiation including the X-ray tube, the control mechanism, the cooling system, and the power source.

21. “Electronic brachytherapy source” means the X-ray tube component used in an electronic brachytherapy device.

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

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

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

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

26. “Gray" or "Gy" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to one (1) joule per kilogram. The previous special

unit of absorbed dose (rad) has been replaced by the gray. [one (1) Gy = one hundred (100) rad].

27. “Half-value layer" or "HVL" means the thickness of a specified material which attenuates X-ray radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one half (1/2) of the value measured without the material at the same point.

28. “Image guided radiation therapy” or “IGRT” means a method of radiation therapy where the treatment setup and delivery are verified through imaging-based system(s).

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

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

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

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

33. “Kilovolt," "kV," "Kilo electron volt," or "keV” means the energy equal to that acquired by a particle with one (1) electron charge in passing through a potential difference of one thousand (1,000) volts in a vacuum. The current convention is to use kV for photons and keV for electrons.

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

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

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

37. “mA” means milliampere.

38. “Medical health physicist” means an individual who meets the qualifications of § 5.3.4 of this Part or is certified by The American Board of Medical Physics in Medical Health Physics, or is certified by the American Board of Health Physics including a minimum three (3) years relevant experience in the subfield of medical health physics.

39. “Megavolt," "MV," "Mega electron volt," or "MeV" means the energy equal to that acquired by a particle with one (1) electron charge in passing through a potential difference of one million (1,000,000) volts in a vacuum. The current convention is to use MV for photons and MeV for electrons.

40. “Mobile electronic brachytherapy” means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

41. “Mobile therapeutic radiation machine” means a machine that is transported from one address to be used at another address, or moveable within the facility of record.

42. "Monitor unit (MU)" (See "Dose monitor unit").

43. “Moving beam radiation therapy” means radiation therapy with any planned displacement of radiation field or patient/human research subject relative to each other, or with any planned change of absorbed dose distribution. It includes, but is not limited to, arc, skip, conformal, intensity modulation and rotational therapy.

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

45. “Patient intervention” means any action by the patient or human research subject, whether intentional or unintentional, during the administration of radiation therapy that causes interference.

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

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

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

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

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

51. "Primary protective barrier" (see "Protective barrier").

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

    a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

    b. "Secondary protective barrier" means the material which attenuates stray radiation.

53. "Qualified medical physicist" means an individual qualified in accordance with § 5.3.4 of this Part.

54. “Quality management program” means a program providing for verification of process by written procedures addressing testing, auditing, and inspection to ensure that deficiencies, deviation, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities.

55. “Radiation detector” means a device that, in the presence of radiation provides, by either direct or indirect means a signal or other indication suitable for use in measuring one (1) or more properties or quantities of incident radiation.

56. "Radiation field" (see "Useful beam").

57. “Radiation head” means the structure from which the useful beam emerges.

58. “Radiation oncology safety team” means a team that must include, but is not limited to, the authorized physician, qualified medical physicist, radiation oncology therapist, and other individuals as deemed necessary by the registrant (e.g., radiation safety officer, chief medical or administrative officer, department administrator/manager, nurse). The radiation oncology safety team is responsible for the registrant’s quality management program.

59. “Radiation protection program” means organizational, procedural, and technical arrangements for the designation of controlled areas and supervised areas, for local rules, and for monitoring of the workplace for occupational exposure.

60. “Redundant beam monitoring system” means a combination of two (2) independent dose monitoring systems in which each system is designed

to terminate irradiation in accordance with a pre-selected number of dose monitor units.

61. “Registrant” means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to this Subchapter and the Act.

62. “Registration” means registration with the Agency pursuant to this Subchapter and the Act.

63. “Safety assessment program” means a plan prepared by the registrant to address protection and safety for radiation practices within the facility and includes, but is not limited to, consideration of the design, construction, and operation of therapeutic radiation machines and related facilities and equipment as they pertain to normal and potential exposure. It also includes consideration of management systems and procedures to safely handle therapeutic radiation machines, to operate equipment, to monitor radiation protection, to implement a quality assurance program, and to handle emergencies.

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

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

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

67. “Sievert" or "Sv" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous special unit of dose equivalent (rem) is being replaced by the sievert. [one (1) Sv = one hundred (100) rem].

68. “Simulator (radiation therapy simulation system)” means any X-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field.

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

70. “Source-skin distance” or “SSD" (See "Target-skin distance").

71. “Stationary beam radiation therapy” means radiation therapy without displacement of one (1) or more mechanical axes relative to the patient/human research subject during irradiation.

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

73. “Survey instruments” means detectors used for measuring radiation exposure levels. Specialized survey instruments are available for detecting different radiation types.

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

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

76. “Tenth-value layer” or “TVL" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth (1/10) of the value measured without the material at the same point.

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

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

79. “Treatment frequency” means fractions per calendar day, minimum interfraction interval, coordination with systemic therapy (if applicable), or plan delivery sequencing. Also known as fractionation schedule.

80. “Treatment modality” means electron, photon, or charged particle modes of delivery.

81. “Treatment site” means the anatomical description of the tissue intended to receive a therapeutic radiation dose, as prescribed in a written directive.

82. “Treatment technique” means a technique that includes, but is not limited to, anteroposterior [AP], posteroanterior [PA], right and/or left laterals, right and/or left anterior or posterior oblique, tangents, 4-field, 3-field, en face, dynamic conformal arc therapy [DCAT], intensity modulated radiation therapy [IMRT], volumetric modulated arc therapy [VMAT], stereotactic

radiosurgery [SRS], stereotactic body radiation therapy [SBRT], or beam configuration approved by the authorized physician.

83. "Tube" means an X-ray tube, unless otherwise specified.

84. "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

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

86. "Virtual simulator" means an imaging unit used in conjunction with relevant software which recreates the treatment machine, and that allows import, manipulation, display, and storage of images from CT and/or other imaging modalities.

87. "Virtual source" means a point from which radiation appears to originate.

88. "Wedge filter" means a filter which effects continuous change in transmission over all or a part of the useful beam.

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

90. "X-ray tube" means any electron tube which is designed to be used primarily for the production of X-rays.

5.3 General Administrative Requirements for Facilities Using Therapeutic Radiation Machines

5.3.1 Administrative Controls

The registrant must be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Agency. The registrant or the registrant's agent must ensure that the requirements of this Part are met in the operation of the therapeutic radiation machine(s).

5.3.2 Prohibition on Use

A therapeutic radiation machine which does not meet the provisions of this Part or has not received U.S. Food and Drug Administration (FDA) clearance or premarket approval, must not be used for irradiation of patients/human research subjects.

5.3.3 Qualification Requirements for Therapeutic Radiation Machine Authorized Physicians

A. The registrant for any therapeutic radiation machine subject to §§ 5.6, 5.7, 5.8, 5.12 or 5.13 of this Part must require the Authorized Physician to be:

1. Currently certified in:

a. Radiation Oncology by the American Board of Radiology (ABR); or

b. Radiation Oncology by the American Osteopathic Board of Radiology(AOBR); or

c. Radiation Oncology by the Royal College of Physicians and Surgeons of Canada.

5.3.4 Qualification Requirements for Medical Physicist

A. The registrant for any therapeutic radiation machine subject to §§ 5.6, 5.7, 5.8, 5.12 or 5.13 of this Part must require the Qualified Medical Physicist to:

1. Be registered with the Agency, under the provisions of Part 3 of this Subchapter, as a provider of clinical radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

2. Be currently certified by the American Board of Radiology in:

a. Therapeutic Radiological Physics; or

b. Radiological Physics; or

c. Therapeutic Medical Physics; or

3. Be currently certified by the American Board of Medical Physics in Radiation Oncology Physics; or

4. Be currently certified by the Canadian College of Physicists in Medicine (CCPM) in Radiation Oncology Physics.

5.3.5 Qualifications of Operators

A. Individuals who will be operating a therapeutic radiation machine for medical use must possess a current license as a Radiation Therapist in accordance with Subchapter 05 Part 34 of this Chapter, Licensure of Radiographers, Nuclear Medicine Technologists, and Radiation Therapists, unless the individual is specifically exempted from licensure by said Regulations.

B. The names and training of all personnel currently operating a therapeutic radiation machine must be kept on file at the facility. Information on former operators must be retained for a period of at least two (2) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

5.3.6 Written Safety Procedures

Written safety procedures, Rules, and posted emergency procedure must be developed by a radiation oncology safety team and must be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator must be able to demonstrate familiarity with these safety procedures, rules, and emergency procedures.

5.3.7 Exposure Prohibited

Individuals must not be exposed to the useful beam except for medical therapy purposes and unless such exposure is justified and has been ordered in writing by a therapeutic radiation machine Authorized Physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing-arts purposes.

5.3.8 Visiting Authorized Physician

A. A registrant may permit any physician to act as a Visiting Authorized Physician under the term of the registrant's Certificate of Registration for up to sixty (60) days per calendar year under the following conditions:

1. The Visiting Authorized Physician has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee (where applicable); and

2. The Visiting Authorized Physician meets the requirements established for Authorized Physician(s) in § 5.3.3 of this Part; and

3. The registrant must maintain copies of the written permission required in § 5.3.8(A)(1) of this Part and documentation that the Visiting Authorized Physician met the requirements of § 5.3.8(A)(2) of this Part for five (5) years from the date of the last visit.

5.3.9 Quality Management Program Training

All individuals associated with the operation of a therapeutic radiation machine must be instructed in and must comply with the provisions of the registrant's safety assessment program, radiation protection program, and quality management program. In addition to the requirements of this Part, these

individuals are also subject to the requirements of §§ 1.7.1, 1.7.5 and 1.10.3 of this Subchapter.

5.3.10 Information and Maintenance Record and Associated Information

A. The registrant must maintain the following information in an auditable form in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:

1. Report of acceptance testing and commissioning.

2. Records of all shielding designs and surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this Part, as well as the date(s) and name(s) of person(s) who performed such activities.

3. Records of maintenance and/or modifications performed on the therapeutic radiation machine as well as the date(s) and name(s) of person(s) who performed such services.

4. Record of the approval process for authorizing the return of the therapeutic radiation machine to clinical use after service, repair, or upgrade, as determined by the radiation oncology safety team.

5.3.11 Records Retention

All records required by this Part must be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in this Part. All required records must be retained in an auditable form in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

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

A. A registrant must report any dose to an embryo/fetus that is greater than fifty (50) mSv (five (5) rem) dose equivalent that is a result of an administration of radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the prescribing physician.

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

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

1. The written report must include:

    a. The registrant's name and registration number;

    b. The name of the prescribing physician;

    c. A brief description of the event;

    d. Why the event occurred;

    e. The effect, if any, on the embryo/fetus;

    f. What actions, if any, have been taken or are planned to prevent recurrence; and

    g. Certification that the registrant notified the pregnant individual or mother (or the mother's responsible relative or guardian), and if not, why not.

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

D. The registrant must provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than twenty-four (24) hours after discovery of an event that would require reporting under §§ 5.3.12(A) of this Part, unless the referring physician personally informs the registrant either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The registrant is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within twenty-four (24) hours, the registrant must make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the embryo/fetus, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If an oral notification is made, the registrant must inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant must provide such a written description if requested.

E. A registrant must:

1. Annotate a copy of the report provided to the Agency with the:

    a. Name of the pregnant individual who is the subject of the event; and

b. Identification number or if no other identification number is available, the social security number of the pregnant individual who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the registrant, no later than fifteen (15) days after the discovery of the event.

5.4 General Technical Requirements for Facilities Using Therapeutic Radiation Machines

5.4.1 Shielding and Safety Designs Requirements

A. Each therapeutic radiation machine subject to §§ 5.6, 5.7, 5.8, 5.12 or 5.13 of this Part must be provided with such primary and/or secondary barriers as are necessary to ensure compliance with Part 1 of this Subchapter.

1. Facility shielding and safety designs must be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies; and

2. By, or under the direction of, a Qualified Medical Physicist or a Medical Health Physicist.

3. Facility design information for all new installations of a therapeutic radiation machine, or installations of a therapeutic radiation machine of a different model with a different isocenter or higher energy or workload into a room not previously approved for that energy or isocenter or planned workload, must be submitted for Agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in § 5.14 of this Part.

B. Radiation Shielding Surveys

1. The registrant must ensure that radiation shielding surveys of all new facilities, and existing facilities not previously surveyed are performed:

a. With an operable radiation measurement survey instrument calibrated in accordance with § 5.11 of this Part; and

b. In accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed; and

c. By, or under the direction of, a Qualified Medical Physicist or a Medical Health Physicist; and

d. Must verify that radiation levels in restricted and unrestricted areas are not likely to cause personnel exposures in excess of the limits specified in Part 1 of this Subchapter.

C. In addition to the requirements of § 5.4.1(A) of this Part, a radiation shielding survey must also be performed prior to any subsequent medical use and:

1. After making any change in the treatment room shielding;

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

3. After replacing or relocating the therapeutic radiation machine; or

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

D. The survey record must indicate all instances where the facility, in the opinion of the Qualified Medical Physicist or Medical Health Physicist, is in violation of applicable regulations. The survey record must also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels in accordance with § 5.11 of this Part, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over any one (1) hour for each restricted and unrestricted area, the calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area, the signature of the individual responsible for conducting the survey, and date signed.

E. If the results of the surveys required by §§ 5.4.1(A) or (B) of this Part indicate any radiation levels in excess of the respective limit specified in § 5.4.1(A) of this Part, the registrant must lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

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

A. If the survey required by § 5.4.1 of this Part indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by §§ 1.8.1(A) and (B) of this Subchapter, before beginning the treatment program the registrant must:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with §§ 1.8.1(A) and (B) of this Subchapter;

2. Perform the survey required by § 5.4.1 of this Part again; and

3. Include in the report required by § 5.4.4 of this Part the results of the initial survey, a description of the modification made to comply with § 5.4.2(A) of this Part and the results of the second (2nd) survey; or

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

5.4.3 Radiation Measuring Equipment

The registrant must have appropriate and operable radiation measuring equipment available for use and calibrated in accordance with § 5.11 of this Part. Radiation measuring equipment includes, but is not limited to, dosimetry systems, survey instruments, and other radiation measuring devices used in planning, guiding, and administering radiation.

5.4.4 Reports of External Beam Radiation Therapy Surveys and Measurements

The registrant for any therapeutic radiation machine subject to §§ 5.6, 5.7, 5.8, 5.12 or 5.13 of this Part must furnish a copy of the records of surveys required in §§ 5.4.1 and 5.4.2 of this Part to the Agency within thirty-six (36) days following completion of the action that initiated the record requirement.

5.5 Quality Management Program

5.5.1 Scope and Applicability

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

1. Written Directives:

   a. A written directive must be dated and signed by an Authorized Physician prior to the administration of radiation;

b. Notwithstanding § 5.5.1(A)(1)(a) of this Part, if, because of the patient's/human research subject's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's/human research subject's health, an oral revision to an existing written directive must be acceptable, provided that the oral revision is documented immediately in writing in the patient's/human research subject's record and a revised written directive is signed by an Authorized Physician within forty-eight (48) hours of the oral revision;

c. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, treatment technique, treatment frequency, and number of fractions.

d. A written revision to an existing written directive may be made provided that the revision is dated and signed by an Authorized Physician prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

e. The registrant must retain a copy of each written directive, in an auditable form, for in accordance with medical record retention requirements for comparable documents after the date of administration.

2. Procedures for Administrations. The registrant must develop, implement, and maintain documented policies, procedures, and rules to provide high confidence that:

a. Prior to the administration of radiation treatments, the patient's/human research subject's identity is verified, by more than one (1) method, as the individual named in the written directive.

b. Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:

(1) Checking the parameters and the results of the primary calculation with a secondary method to verify they are correct and in accordance with the written directive; and

(2) Verifying the planned parameters are correctly displayed on the consoles of therapeutic radiation machines;

c. Each administration is in accordance with the written directive; and

d. Any unintended treatment deviation from the written directive, or final plan of treatment utilized as a written directive, is identified, and evaluated, and appropriate action is taken.

e. At least two (2) radiation therapists per patient are required when non-emergent external beam radiation therapy is being delivered.

3. A registrant must retain a copy of the procedures required by § 5.5.1(A)(2) of this Part for the duration of the registration.

5.5.2 Notifications of Medical Events

A. A registrant must report any medical event, except for a medical event resulting from intervention by a patient or human research subject, in which the administration of therapeutic radiation machine radiation results or will likely result in unintended permanent functional damage to an organ or a physiological system as determined by an Authorized Physician as defined in § 5.3.3 of this Part.

B. Other than events that result from intervention by a patient or human research subject, a registrant must report any event in which the administration of a therapeutic radiation machine therapy dose:

1. Involves the wrong patient, wrong treatment modality, wrong treatment technique, wrong treatment site; or

2. The administered dose differs from the prescribed dose as stated in the written directive by more than fifty percent (50%) for treatment courses consisting of a single fraction; or

3. The administered dose differs from the prescribed dose as stated in the written directive by more than ten percent (10%) for treatment courses consisting of five (5) fractions or less; or

4. The administered dose over any five (5) consecutive fractions differs from the prescribed dose by more than thirty percent (30%); or

5. The administered dose over the entire treatment course consisting of more than five (5) fractions differs from the prescribed dose by more than twenty percent (20%).

C. The registrant must notify the Agency no later than the next business day after the registrant ascertains that a medical event occurred.

1. All required notifications must use Agency contact information specified in § 1.4 of this Subchapter.

D. The registrant must submit a written report to the Agency within fifteen (15) days after the initial notification of a medical event. The written report must include:

1. The registrant's name and registration number;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect, if any, on the individual(s);

6. Actions, if any, that have been taken, or are planned, to prevent recurrence; and

7. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

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

F. The prescribing Authorized Physician must provide notification of the event to the individual who is the subject of the medical event no later than twenty-four (24) hours after initial notification by the registrant to the Agency, unless the prescribing Authorized Physician determines that, based on medical judgement, telling the individual would be harmful. The prescribing Authorized Physician will also notify any other physician health care providers actively involved in the patient's care for the disease that is being treated. If the health care providers or the affected individual cannot be reached within twenty-four (24) hours, the prescribing Authorized Physician must notify each as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification.

G. To meet the requirements of § 5.5.2 of this Part, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If an oral notification is made, the registrant must inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant must provide such a written description if requested.

H. Aside from the notification requirement, nothing in § 5.5.2 of this Part affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

I. The registrant must retain a record of each medical event report with an identification link to the individual who is the subject of the medical event in accordance with § 5.5.3 of this Part.

5.5.3 Records of Medical Events

A. A registrant must retain a record of medical events reported in accordance with § 5.5.2 of this Part for the duration of the registration. The identification link must include, as a minimum:

1. The name of the individual who is the subject of the medical event; and

2. The social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event.

B. A registrant must provide a copy of the annotated report to the referring physician, if other than the registrant, no later than fifteen (15) days after the registrant ascertains that a medical event occurred.

5.5.4 Implementation of Quality Management Program

A. As a part of the quality management program, the registrant must:

1. Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient/human research subject administrations, and all medical events to verify compliance with all aspects of the quality management program.

2. Conduct these reviews at intervals not to exceed twelve (12) months.

3. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of § 5.5.1 of this Part; and

4. Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for three (3) years.

5.5.5 [RESERVED]

5.5.6 Modifications

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

5.6 Therapeutic Radiation Machines of Less Than 500 kV

Documentation from the manufacturer and installer that the therapeutic radiation machine was manufactured and installed in accordance with most current applicable International Electrotechnical Commission (IEC) standards in effect at the time of manufacturing/installation must be sufficient to demonstrate compliance with the applicable requirements of §§ 5.6.1 through 5.6.13 of this Part.

5.6.1 Leakage Radiation

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

1. Five to fifty (5 – 50) kV Systems. The leakage air kerma rate measured at any position five (5) centimeters from the tube housing assembly must not exceed one (1) mGy (one hundred (100) mrad) in any one (1) hour.

2. Greater than fifty (>50) and < five hundred (500) kV Systems. The leakage air kerma rate measured at a distance of one (1) meter from the target in any direction must not exceed one (1) cGy in any one (1) hour. This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters (100 cm^2). In addition, the air kerma rate at a distance of five (5) centimeters from the surface of the tube housing assembly must not exceed thirty (30) cGy per hour.

3. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in §§ 5.6.1(A)(1) and (2) of this Part for the specified operating conditions. Records on leakage radiation measurements must be maintained in an auditable form at the installation for inspection by the Agency.

5.6.2 Permanent Beam Limiting Devices

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

5.6.3 Adjustable or Removable Beam Limiting Devices

A. All adjustable or removable beam limiting devices, diaphragms, cones or blocks must not transmit more than five percent (5%) of the useful beam for the most penetrating beam used.

B. When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field.

5.6.4 Filter System

A. The filter system must be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. An interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot must not exceed one (1) cGy per hour at one (1) meter under any operating conditions; and

4. Each filter must be marked as to its material of construction and its thickness.

5.6.5 Tube Immobilization

A. The X-ray tube must be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

B. The tube housing assembly must be capable of being immobilized for stationary portal treatments.

5.6.6 Source Marking

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

5.6.7 Beam Block

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

5.6.8 Timer

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

B. A timer which has a display must be provided at the treatment control panel. The timer must have a pre-set time selector and an elapsed time or time remaining indicator.

C. The timer must be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator.

D. The timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

E. The timer must permit accurate pre-setting and determination of exposure times as short as one (1) second.

F. The timer must not permit an exposure if set at zero (0).

G. The timer must not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

H. Timer must be accurate to within one percent (1%) of the selected value or one (1) second, whichever is greater.

5.6.9 Control Panel Functions

A. The control panel, in addition to the displays required by other provisions in § 5.6 of this Part, must have:

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

2. An indication of whether X-rays are being produced.

3. Means for indicating X-ray tube potential and current.

4. The means for terminating an exposure at any time.

5. An access control device which will prevent unauthorized use of the therapeutic radiation machine; and

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

5.6.10 Multiple Tubes

A. When a control panel may energize more than one (1) X-ray tube:

1. It must be possible to activate only one (1) X-ray tube at any time;

2. There must be an indication at the control panel identifying which X-ray tube is activated; and

3. There must be an indication at the tube housing assembly when that tube is energized.

5.6.11 Target-to-Skin Distance (TSD)

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

5.6.12 Shutters

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

5.6.13 Low Filtration X-ray Tubes

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

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

A. In addition to shielding adequate to meet requirements of § 5.9.1 of this Part, the treatment room must meet the following design requirements:

1. Aural Communication. Provision must be made for continuous two (2) way aural communication between the patient/human research subject and the operator at the control panel.

2. Viewing Systems. Provision must be made to permit continuous observation of the patient/human research subject during irradiation and the viewing system must be so located that the operator can observe the patient/human research subject from the control panel. The therapeutic radiation machine must not be used for patient/human research subject irradiation unless at least one (1) viewing system is operational.

5.6.15 Additional Requirements

A. Treatment rooms which contain a therapeutic radiation machine capable of operating above one hundred fifty (150) kV must meet the following additional requirements:

1. All protective barriers must be fixed except for entrance doors or beam interceptors.

2. The control panel must be located in a location that ensures compliance with Part 1 of this Subchapter.

3. Interlocks must be provided such that all entrance doors, including doors to any interior booths, must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in § 5.6.15(A)(3) of this Part is opened while the X-ray tube is activated, the air kerma rate at a distance of one (1) meter from the source must be reduced to less than one (1) mGy (one hundred (100) mrad) per hour.

5.6.16 Acceptance Testing, Commissioning, and Full Calibration Measurements

A. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to § 5.6 of this Part must be performed by, or under the direct supervision of, a Qualified Medical Physicist.

1. Acceptance testing and commissioning must be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed. Acceptance testing and commissioning must be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

2. Full calibration must be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed. All applicable parameters (for all energies), and the calibration report, must be completed:

a. Before the first medical use following installation or reinstallation of the therapeutic radiation machine; and

b. At intervals not exceeding thirteen (13) calendar months; and

c. Before medical use under the following conditions:

(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent

(5%) from the value obtained at the last full calibration and the difference cannot be reconciled; and

(2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

3. Notwithstanding the requirements of § 5.6.16(A)(2)(c) of this Part:

a. Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and

b. If the repair, replacement or modification does not affect all energies, full calibration must be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in § 5.6.16(A)(2)(c)(1) of this Part.

B. The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include the calibration reports, the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Qualified Medical Physicist responsible for performing the calibration.

5.6.17 Quality Assurance Checks

A. Periodic quality assurance checks must be performed on therapeutic radiation machines subject to § 5.6 of this Part, which are capable of operation at greater than or equal to fifty (50) kV.

B. To satisfy the requirement of § 5.6.17(A) of this Part, periodic quality assurance checks must meet the following requirements:

1. The registrant must perform periodic quality assurance checks in accordance with written procedures established by the Qualified Medical Physicist and must be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer’s protocol or equivalent quality, safety, and security protocols, must be followed; and

2. The periodic quality assurance check procedures must specify the frequency at which tests or measurements are to be performed. The periodic quality assurance check procedures must specify that the periodic

quality assurance check must be performed during the calibration specified in § 5.6.16(A) of this Part. The acceptable tolerance for each parameter measured in the periodic quality assurance checks, when compared to the value for that parameter determined in the calibration specified in § 5.6.16(A) of this Part, must be stated.

C. The cause for a parameter exceeding a tolerance set by the Qualified Medical Physicist and consistent with nationally recognized standards must be investigated and corrected before the system is used for patient/human research subject irradiation.

D. Whenever a periodic quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Qualified Medical Physicist's periodic quality assurance check procedures, the system must be recalibrated, as required in § 5.6.16(A) of this Part.

E. The registrant must use the dosimetry system described in § 5.11.5 of this Part to make the periodic absolute dose measurement.

F. The registrant must have the Qualified Medical Physicist review and sign the results of each radiation output quality assurance check within fifteen (15) days of the date that the check was performed.

G. The registrant must ensure that monthly safety quality assurance checks of therapeutic radiation machines subject to § 5.6 of this Part are performed at intervals not to exceed thirty-six (36) days.

H. Notwithstanding the requirements of §§ 5.6.17(F) and (G) of this Part, the registrant must ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by §§ 5.6.17(F) and (G) of this Part have been performed at intervals not to exceed the thirty-six (36) day period immediately prior to said administration.

I. To satisfy the requirement of § 5.6.17(G) of this Part, monthly safety quality assurance checks must ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the "BEAM-ON" and termination switches;

3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

4. Viewing and aural systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room;

J. The registrant must maintain a record of each quality assurance check in an auditable form for three (3) years. The record must include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number, serial number, and calibration report of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the quality assurance check.

5.6.18 Operating Procedures

A. The therapeutic radiation machine must not be used for irradiation of patients/human research subjects unless the requirements of §§ 5.6.16 and 5.6.17 of this Part have been met.

B. Therapeutic radiation machines must not be left unattended unless secured pursuant to § 5.6.9(A)(5) of this Part.

C. When a patient/human research subject must be held in position for radiation therapy, mechanical support or restraints devices must be used.

D. The tube housing or any other part of the imaging assembly must not be held by an individual or patient during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed fifty (50) kV. In such cases, the holder must wear protective gloves and apron of not less than one half (0.5) millimeters lead equivalency at one hundred (100) kV.

E. A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console; and

F. No individual other than the patient/human research subject must be in the treatment room during exposures from therapeutic radiation machines operating above one hundred fifty (150) kV. At energies less than or equal to one hundred fifty (150) kV, any individual, other than the patient/human research subject, in the treatment room must be protected by a barrier sufficient to meet the requirements of § 1.7.1 of this Subchapter.

5.6.19 Possession of Survey Instrument(s)

Each facility location authorized to use a therapeutic radiation machine in accordance with § 5.6 of this Part must possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten (10) µSv (one (1) mrem) per hour to ten (10) mSv (one thousand (1,000) mrem) per hour or exposure rates over the range five hundred (500) uR/h to five (5) R/h. The survey instrument(s) must be operable and calibrated in accordance with § 5.11 of this Part.

5.7 Therapeutic Radiation Machines – Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)

Documentation from the manufacturer and installer that the therapeutic radiation machine was manufactured and installed in accordance with most current applicable IEC standards in effect at the time of manufacturing/installation must be sufficient to demonstrate compliance with the applicable requirements of §§ 5.7.2 through 5.7.16 of this Part.

5.7.1 [RESERVED]

5.7.2 Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes

A. For each therapeutic radiation machine subject to § 5.7 of this Part, the registrant must determine, or obtain from the manufacturer, the leakage radiation for the specified operating conditions. Records on leakage radiation measurements must be maintained in an auditable form at the installation for inspection by the Agency.

B. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two (2) meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient/human research subject plane), must not exceed a maximum of two tenths of one percent (0.2%) and an average of one tenth of one percent (0.1%) of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding one hundred square centimeters (100 cm^2) at a minimum of sixteen (16) points uniformly distributed in the plane.

C. Except for the area defined in § 5.7.2 of this Part, the absorbed dose due to leakage radiation (excluding neutrons) at one (1) meter from the electron path between the electron source and the target or electron window must not exceed one half of one percent (0.5%) of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding one hundred square centimeters (100 cm^2).

D. The neutron absorbed dose outside the useful beam must be in compliance with the appropriate manufacturer specifications; and

E. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in §§ 5.7.2(A) through (D) of this Part for the specified operating conditions. Records on leakage radiation measurements must be maintained in an auditable form at the installation for inspection by the Agency.

5.7.3 Leakage Radiation Through Beam Limiting Devices

A. Photon Radiation. All adjustable or interchangeable beam limiting devices must attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) must not exceed two percent (2%) of the maximum absorbed dose on the central axis of the useful beam measured in a one hundred square centimeter (100 cm^2) radiation field, or maximum available field size if less than one hundred square centimeters (100 cm^2).

B. Electron Radiation. All adjustable or interchangeable electron applicators must attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance must not exceed:

1. A maximum of two percent (2%) and average of one half of one percent (0.5%) of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line seven (7) centimeters outside the periphery of the useful beam; and

2. A maximum of ten percent (10%) of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line two (2) centimeters outside the periphery of the useful beam.

C. Measurement of Leakage Radiation

1. Photon Radiation. Measurements of leakage radiation through the beam limiting devices must 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 must be measured independently at the depth of maximum dose. Measurements must 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 must 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 must be made using one (1) centimeter of water equivalent build up material.

5.7.4 Filters/Wedges

A. If applicable, each wedge filter which is removable from the system must be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle must appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge must be removed from clinical service.

B. If the absorbed dose rate information required by § 5.7.2 of this Part relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter must be removable only by the use of tools.

C. If applicable, for equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

1. Irradiation must 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 must be provided to prevent irradiation if the filter selected is not in the correct position;

3. A display must 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 must be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

5.7.5 Stray Radiation in the Useful Beam

The registrant must obtain from the manufacturer data sufficient to ensure that stray X-ray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with the appropriate manufacturer specifications and perform as intended.

5.7.6 Beam Monitors

A. All therapeutic radiation machines subject to § 5.7 of this Part must be provided with redundant beam monitoring systems. The detectors for these systems must be fixed and functional in the useful beam during treatment to indicate the dose monitor unit rate.

B. Equipment must be provided with at least two (2) independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

C. Equipment must be provided with at least one (1) radiation detector. This detector must be incorporated into a useful beam monitoring system.

D. The detector and the system into which that detector is incorporated must meet the following requirements:

1. Each detector must be removable only with tools and, if movable, must be interlocked to prevent incorrect positioning;

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

3. Each beam monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation; and

4. The design of the beam monitoring systems must ensure that the:

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

b. Failure of either system must terminate irradiation or prevent the initiation of radiation.

5. Each beam monitoring system must have a legible display at the treatment control panel. Each display must:

a. Maintain a reading until intentionally reset;

b. Have only one (1) scale and no electrical or mechanical scale multiplying factors;

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

d. In the event of power failure, the beam monitoring information required in § 5.7.6(D)(5)(c) of this Part displayed at the control panel at the time of failure must be retrievable in at least one system for a twenty (20) minute period of time.

5.7.7 Beam Flatness and Symmetry

Beam flatness and symmetry must be in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed.

5.7.8 Selection and Display of Dose Monitor Units

A. Irradiation must not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

B. The pre-selected number of dose monitor units must be displayed at the treatment control panel until reset for the next irradiation.

C. After termination of irradiation, it must be necessary to reset the treatment delivery parameters before subsequent treatment can be initiated; and

D. After interruption of irradiation, it must be necessary for the operator to follow the manufacturer and facility procedures before irradiation can be re-initiated.

5.7.9 Air Kerma Rate/Absorbed Dose Rate

A. A system must be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in § 5.7.6 of this Part may form part of this system. In addition:

1. The dose monitor unit rate must be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device must be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated must be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device must be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four (4) Gy; and

4. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the maximum value(s) specified in §§ 5.7.9(A)(2) and (3) of this Part for the specified operating conditions. Records of these maximum value(s) must be maintained in an auditable form at the installation for inspection by the Agency.

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

A. Each primary system must terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

B. If the original design of the equipment included a secondary dose monitoring system, that system must be capable of terminating irradiation when not more than fifteen percent (15%) or forty (40) dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

C. An indicator on the control panel must show which monitoring system has terminated irradiation.

5.7.11 Termination of Irradiation

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

5.7.12 Interruption of Irradiation

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

5.7.13 Irradiation Control Device

A. A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval or pre-set number of monitor units.

B. If applicable, a timer must be provided which has a display at the treatment control panel. The timer must have a pre-set time selector and an elapsed time indicator.

C. The timer or monitor unit indicator must be a cumulative device which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator.

D. The timer or monitor unit indicator must terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

5.7.14 Selection of Radiation Type

A. Equipment capable of both X-ray therapy and electron therapy must meet the following additional requirements:

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

2. The radiation type selected must be displayed at the treatment control panel before and during irradiation;

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

4. An interlock system must be provided to prevent irradiation with X-rays, except to obtain an image, when electron applicators are fitted;

5. An interlock system must be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

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

5.7.15 Selection of Energy

A. Equipment capable of generating radiation beams of different energies must meet the following requirements:

1. Irradiation must not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected must be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it must be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

3. Irradiation must not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

4. The selection of energy must be in compliance with the appropriate manufacturer specifications and perform as intended.

5.7.16 Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy

A. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy must meet the following requirements:

1. Irradiation must not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel.

2. The mode of operation must be displayed at the treatment control panel.

3. An interlock system must be provided to ensure that the equipment can operate only in the mode which has been selected.

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

5. Moving beam radiation therapy must be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement:

    a. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than five percent (5%) from the dose monitor unit value selected;

    b. An interlock must be provided to prevent motion of more than five degrees (5°) or one (1) cm beyond the selected limits during moving beam radiation therapy;

    c. An interlock must be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

    d. An interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees (10°) of rotation or one (1) cm of linear motion differs by more than twenty percent (20%) from the selected value;

    e. Moving beam radiation therapy must be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation must be as required by § 5.7.10 of this Part.

7. An interlock system must be provided to terminate irradiation if movement:

    a. Occurs during stationary beam radiation therapy; or

b. Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

8. In addition to the above requirements, facilities using equipment where the radiation therapy source is mounted on a ring gantry must develop a quality assurance program in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed.

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

A. In addition to shielding adequate to meet requirements of § 5.9 of this Part, the following design requirements are also applicable:

1. Protective Barriers. All protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors.

2. Control Panel. In addition to other requirements specified in this Part, the control panel must also:

a. Be in a location that ensures compliance with Part 1 of this Subchapter;

b. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

c. Provide an indication of whether radiation is being produced; and

d. Include an access control system which will prevent unauthorized use of the therapeutic radiation machine.

3. Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system must be provided to permit continuous observation of the patient/human research subject following positioning and during irradiation and must be so located that the operator may observe the patient/human research subject from the treatment control panel. The therapeutic radiation machine must not be used for patient/human research subject irradiation unless at least one (1) viewing system is operational.

4. Aural Communications. Provision must be made for continuous two (2) way aural communication between the patient/human research subject and the operator at the control panel. The therapeutic radiation machine

must not be used for irradiation of patients/human research subjects unless continuous two (2) way aural communication is possible.

5. Room Entrances. Treatment room entrances must 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."

6. Entrance Interlocks. Interlocks must 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 must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

7. 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 (B) of this Subchapter, interlocks must 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).

8. Emergency Cutoff Switches. At least one (1) emergency power cutoff switch must terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination capability required by § 5.7.11 of this Part. All emergency power cutoff switches must 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.

9. Safety Interlocks. All safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

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

5.7.18 Qualified Medical Physicist Support

A. The services of a Qualified Medical Physicist must be required in facilities having therapeutic radiation machines with energies of five hundred (500) kV and above. The Qualified Medical Physicist must be responsible for:

1. Full calibration(s) required by § 5.7.20 of this Part and protection surveys required by § 5.4.1 of this Part;

2. Supervision and review of dosimetry;

3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by § 5.7.21(C) of this Part;

5. Consultation with the Authorized Physician in treatment planning, as needed; and

6. Performing calculations/assessments regarding medical events and unintended treatment deviations.

B. If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by § 5.7.19 of this Part must also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

5.7.19 Operating Procedures

A. No individual, other than the patient/human research subject, must be in the treatment room during treatment or during any irradiation for testing or calibration purposes.

B. Therapeutic radiation machines must not be made available for medical use unless the requirements of §§ 5.4.1, 5.7.20 and 5.7.21 of this Part have been met.

C. Therapeutic radiation machines, when not in operation, must be secured to prevent unauthorized access and use.

D. When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field where applicable.

E. If a patient/human research subject must be held in position during treatment, mechanical support or restraint devices must be used.

F. A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console.

5.7.20 Acceptance Testing, Commissioning and Full Calibration Measurements

A. Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to § 5.7 of this Part must be performed under the supervision of a Qualified Medical Physicist and reviewed and approved by a Qualified Medical Physicist.

B. Acceptance testing and commissioning must be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed. Acceptance testing and commissioning must be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

C. Full calibration must be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed. All applicable parameters (for all energies) must be completed at intervals not exceeding (13) calendar months.

1. Full calibration must include external validation of machine output accuracy for all energies prior to clinical use and at least annually thereafter for photons and protons, and every two (2) years for electrons.

D. The Qualified Medical Physicist must perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

1. Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent (5%) from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities must only require measurements for those modes and/or energies that are not within their acceptable range; and

2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements must be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in § 5.7.20(D)(1) of this Part.

E. The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers, serial numbers, and calibration reports of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Qualified Medical Physicist responsible for performance of the calibration.

F. Therapy-Related Computer Systems. The registrant must perform acceptance testing on the treatment planning system of therapeutic radiation machine-related computer systems in accordance with current published recommendations from a recognized national professional association (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol must be followed.

1. Acceptance testing must be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing must include, as applicable, verification of:

   a. The source-specific input parameters required by the dose calculation algorithm;

   b. The accuracy of dose calculations at representative points;

   c. The accuracy of isodose plots and graphic displays;

   d. The accuracy of the software used to determine radiation source positions from radiographic images; and

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

2. Prior to each patient treatment regimen, the parameters for the treatment must be evaluated and approved by the Authorized Physician and the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

5.7.21 Quality Assurance Checks

A. Periodic quality assurance checks must be performed on all therapeutic radiation machines subject to § 5.7 of this Part, which are capable of operation at greater than or equal to five hundred (500) kV. Periodic quality assurance checks must meet the following requirements:

1. The registrant must use a dosimetry system which has calibrated in accordance with § 5.11.5 of this Part to make the periodic quality assurance checks required in § 5.7.21(A) of this Part.

2. The registrant must perform periodic quality assurance checks required by § 5.7.21(A) of this Part in accordance with written procedures established by the Qualified Medical Physicist and must be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized

national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed.

B. The registrant must review the results of each periodic radiation output check according to the following procedures:

1. The Authorized Physician or Qualified Medical Physicist must be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine must not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

2. If all periodic radiation output quality assurance check parameters appear to be within their acceptable range, the periodic quality assurance check must be reviewed and signed by either the Authorized Physician or Qualified Medical Physicist within five (5) treatment days; and

3. The Qualified Medical Physicist must review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty-six (36) days.

C. Therapeutic radiation machines subject to § 5.7 of this Part must have applicable safety quality assurance checks that meet the following requirements:

1. The registrant must perform safety quality assurance checks in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed; and

2. Safety quality assurance checks must be performed at intervals not to exceed one (1) week; and

3. Safety quality assurance checks must ensure proper operation of:

a. Proper operation of the "BEAM-ON", interrupt and termination switches;

b. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

c. Electrically operated treatment room door(s) from inside and outside the treatment room.

d. Viewing and aural systems.

e. Electrical interlocks at each external beam radiation therapy room entrance.

f. At least one (1) termination switch. If more than one (1) termination switch is installed and not all switches are tested at once, each switch must be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted as recommended by the manufacturer in order to minimize possible stability problems with the therapeutic radiation machine.

D. The registrant must promptly repair any system identified in §§ 5.7.21(A) and (D) of this Part that is not operating properly.

E. The registrant must maintain a record of each quality assurance check required by §§ 5.7.21(A) and (D) of this Part for three (3) years. The record must include the date of the quality assurance check, the manufacturer's name, model number, serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number, and calibration report of the appropriate instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

5.7.22 Accreditation and External Audits

A. Each registrant providing radiation therapy with therapeutic radiation machines must:

1. Maintain an accreditation in radiation oncology by the American College of Radiology (ACR), American College of Radiation Oncology (ACRO), American Society for Radiation Oncology (ASTRO), or an accrediting organization that is recognized by the Agency; or

2. Conduct an external audit as described in § 5.7.22(B) of this Part.

B. An external audit must be completed by an Authorized Physician and Qualified Medical Physicist. This audit must be conducted at intervals not exceeding thirty-six (36) months and when new technology and/or features are used. The auditing Authorized Physician and Qualified Medical Physicist must be external.

1. The Authorized Physician audit requirement consists of a review of all the clinical aspects of the practice such as patient management (medical record review), including treatment response seen in follow-up visits if appropriate, and assessment of staffing levels including physician assistants, therapists and nurses based on patient volume and technology and complexity of services provided at the facility. The reviewing Authorized Physician must meet the requirements of § 5.3.3 of this Part.

2. The Qualified Medical Physicist audit requirement consists of a review of the QA manual and records, policies and procedures and an assessment of staffing, training and equipment needs. The reviewing Qualified Medical Physicist must meet the requirements of § 5.3.4 of this Part.

3. At a minimum, the external audit must address general questions about the practice including:

   a. Therapy modalities;

   b. Facility staffing;

   c. Patient simulation and treatment;

   d. A review of patient charts and images completed by an Authorized Physician who is active in the practice and type of radiation therapy offered by the registrant;

   e. A physics component completed by a Qualified Medical Physicist who is active in the practice of the technology and modalities in use at the practice under audit;

   f. An audit summary and recommendations as well as the facility's response.

4. Agency Form RCA-14 describes the minimum elements that must be included in an external audit.

C. For a newly registered facility, an initiation for accreditation or external audit must be no later than six (6) months after patient treatment begins.

D. The outcome of the accreditation survey or external audit or must be available for inspection and provided to the Agency upon request.

5.8 Electronic Brachytherapy

Documentation from the manufacturer and installer that the therapeutic radiation machine was manufactured and installed in accordance with most current applicable IEC standards in effect at the time of manufacturing/installation must be sufficient to demonstrate compliance with the applicable requirements of §§ 5.8.4 through 5.8.6 of this Part.

5.8.1 Applicability

A. Electronic brachytherapy devices must be subject to the requirements of § 5.8 of this Part, and must be exempt for the requirements of § 5.6 of this Part.

B. An electronic brachytherapy device that does not meet the requirements of § 5.8 of this Part must not be used for irradiation of patients.

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

5.8.2 Possession of Survey Instrument(s)

Each facility location authorized to use an electronic brachytherapy device in accordance with § 5.8 of this Part must possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten (10) µSv (one (1) mrem) per hour to ten (10) mSv (one thousand (1,000) mrem) per hour. The survey instrument(s) must be operable and calibrated in accordance with § 5.11 of this Part for the applicable electronic brachytherapy source energy.

5.8.3 Facility Design Requirements for Electronic Brachytherapy Devices

A. In addition to shielding adequate to meet requirements of § 5.9 of this Part, the treatment room must meet the following design requirements:

1. If applicable, provision must be made to prevent simultaneous operation of more than one (1) therapeutic radiation machine in a treatment room.

2. Access to the treatment room must be controlled by a door at each entrance.

3. Provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device must not be used for patient irradiation unless the patient can be observed.

4. For electronic brachytherapy devices capable of operating at fifty (50) kV and below, radiation shielding for the staff in the treatment room must be available, either as a portable shield and/or as localized shielded material around the treatment site.

5. For electronic brachytherapy devices capable of operating at greater than one hundred fifty (150) kV:

    a. The control panel must be located outside the treatment room;

    b. Electrical interlocks must be provided for all doors to the treatment room that will:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source to be shielded or switched off when an entrance door is opened; and

(3) Prevent the source from being exposed or switched on following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

5.8.4 Electrical Safety for Electronic Brachytherapy Devices

A. The high voltage transformer must be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

B. The high voltage transformer must be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

C. The high voltage transformer must have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.

D. Equipment must be in compliance with the appropriate manufacturer specifications and perform as intended:

5.8.5 Control Panel Functions

A. The control panel, in addition to the displays required by other provisions in § 5.8 of this Part, must:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

2. Provide an indication of whether X-rays are being produced;

3. Provide a means for indicating electronic brachytherapy source potential and current;

4. Provide the means for terminating an exposure at any time; and

5. Include an access control device that will prevent unauthorized use of the electronic brachytherapy device.

5.8.6 Irradiation Control Device

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

B. A timer must be provided at the treatment control panel. The timer must indicate the planned setting and the time elapsed or remaining.

C. The timer must not permit an exposure if set at zero (0).

D. The timer must be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator.

E. The timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.

F. The timer must permit setting of exposure times as short as one tenth of one (0.1) second.

G. The timer must be accurate to within one percent (1%) of the selected value or one tenth of one (0.1) second, whichever is greater.

5.8.7 Qualified Medical Physicist Support

A. The services of a Qualified Medical Physicist must be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist must be responsible for:

1. Evaluation of the output from the electronic brachytherapy source;

2. Generation of the necessary dosimetric information;

3. Supervision and review of treatment calculations prior to initial treatment of any treatment site;

4. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in § 5.8.11 of this Part;

5. Consultation with the Authorized Physician in treatment planning, as needed; and

6. Performing calculations/assessments regarding patient treatments that may constitute a medical event.

B. If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by § 5.8.8 of this Part must also specifically address how the Qualified Medical Physicist is to be contacted for problems or

emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

5.8.8 Operating Procedures

A. Only individuals approved by the Authorized Physician, Radiation Safety Officer, or Qualified Medical Physicist must be present in the treatment room during treatment.

B. Electronic brachytherapy devices must not be made available for medical use unless the requirements of §§ 5.4, 5.8.9 and 5.8.10 of this Part have been met.

C. The electronic brachytherapy device must be rendered inoperable, either by hardware or other access control system, when unattended by qualified staff or service personnel.

D. During operation, the electronic brachytherapy device operator must monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent unshielded exposure from the treatment beam.

E. If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used.

F. Written procedures must be developed, implemented, and maintained for responding to an abnormal situation. These procedures must include:

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

2. The names and telephone numbers of the Authorized Physicians, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

G. A copy of the current operating and emergency procedures must be physically located at the electronic brachytherapy device control console.

1. If the control console is integral to the electronic brachytherapy device, the required procedures must be kept where the operator is located during electronic brachytherapy device operation.

H. Instructions must be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the Authorized Physicians, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

I. The Radiation Safety Officer, or his/her designee, and an Authorized Physician must be notified as soon as possible if the patient has a medical emergency,

suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist must inform the manufacturer of the event.

5.8.9 Safety Precautions for Electronic Brachytherapy Devices

A. A Qualified Medical Physicist must determine which persons in the treatment room require monitoring when the beam is energized;

B. An Authorized Physician and a Qualified Medical Physicist must be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

C. A Qualified Medical Physicist and either an Authorized Physician or a physician or electronic brachytherapy device operator, under the supervision of an Authorized Physician, who has been trained in the operation and emergency response for the electronic brachytherapy device, must be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

D. When shielding is required by § 5.8.3(A)(4) of this Part, the electronic brachytherapy device operator must use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist must designate shield locations sufficient to meet the requirements of § 1.7.1 of this Subchapter for any individual, other than the patient, in the treatment room; and

E. All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist must approve any deviation from this requirement and must designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

5.8.10 Electronic Brachytherapy Source Calibration Measurements

A. Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to § 5.8 of this Part must be performed by, or under the direct supervision of, a Qualified Medical Physicist;

B. Calibration of the electronic brachytherapy source output must be made for each electronic brachytherapy source, or after any repair affecting the X-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

C. Calibration of the electronic brachytherapy source output must utilize a dosimetry system as described in § 5.4.3 of this Part;

D. Calibration of the electronic brachytherapy source output must be in accordance with current published recommendations from a recognized national professional association with expertise in the use of electronic brachytherapy. In the absence

of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed.

E. The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include:

1. The date of the calibration;

2. The manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source;

3. The model numbers, serial numbers, and calibration reports of the instrument(s) used to calibrate the electronic brachytherapy device; and

4. The name and signature of the Qualified Medical Physicist responsible for performing the calibration.

5.8.11 Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices

A. Quality assurance checks must be performed on each electronic brachytherapy device subject to § 5.8 of this Part:

1. At the beginning of each day of use.

2. Each time the device is moved to a new room or site. Site is intended to include each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer. See § 5.8.14 of this Part for additional clarification.

3. After each X-ray tube installation.

B. The registrant must perform periodic quality assurance checks required by § 5.8.11(A) of this Part consistent with manufacturer guidance and procedures established by the Qualified Medical Physicist.

C. To satisfy the requirements of § 5.8.11(A) of this Part, radiation output quality assurance checks must be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of electronic brachytherapy. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed.

D. The registrant must use a dosimetry system that has been intercompared within the previous twelve (12) months with the dosimetry system described in § 5.4.3

of this Part to make the quality assurance checks required in § 5.8.11(C) of this Part;

E. The registrant must review the results of each radiation output quality assurance check according to the following procedures:

1. An Authorized Physician and Qualified Medical Physicist must be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device must not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

2. If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check must be reviewed and signed by either the Authorized Physician or Qualified Medical Physicist within two (2) days; and

3. The Qualified Medical Physicist must review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty (30) days.

F. To satisfy the requirements of § 5.8.11(A) of this Part, safety device quality assurance checks must, at a minimum, assure:

1. Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

2. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

3. Proper operation of radiation monitors, if applicable;

4. The integrity of all cables, catheters or parts of the device that carry high voltages; and

5. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

G. If the results of the safety device quality assurance checks required in § 5.8.11(F) of this Part indicate any malfunction, a registrant must secure the control console in the "OFF" position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

H. The registrant must maintain a record of each quality assurance check required by §§ 5.8.11(C) and (F) of this Part in an auditable form for three (3) years.

1. The record must include the date of the quality assurance check, the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check and the name and signature of the Qualified Medical Physicist who reviewed the quality assurance check;

2. For radiation output quality assurance checks required by § 5.8.11(C) of this Part, the record must also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

5.8.12 Therapy-Related Computer Systems

A. The registrant must perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in the use of electronic brachytherapy. In the absence of an acceptance testing protocol published by a recognized national professional association, the manufacturer's acceptance testing protocol must be followed.

B. Acceptance testing must be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing must include, as applicable, verification of:

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

2. The applicator-specific input parameters required by the dose calculation algorithm;

3. The accuracy of dose, dwell time, and treatment time calculations at representative points;

4. The accuracy of isodose plots and graphic displays;

5. The accuracy of the software used to determine radiation source positions from radiographic images; and

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

C. The position indicators in the applicator must be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

D. Prior to each patient treatment regimen, the parameters for the treatment must be evaluated and approved by the Authorized Physician and the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

5.8.13 Training

A. A registrant must provide instruction, initially and at intervals not to exceed twelve (12) months, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in § 5.8.8 of this Part. If the interval between patients exceeds twelve (12) months, retraining of the individuals must be provided before the next treatment is administered.

B. In addition to the requirements of § 5.3.3 of this Part for therapeutic radiation machine Authorized Physicians and § 5.3.4 of this Part for Qualified Medical Physicists, these individuals must also receive device specific instruction initially from the manufacturer, and at intervals not to exceed twelve (12) months from either the manufacturer or other qualified trainer. The training must be of a duration recommended by a recognized national professional association with expertise in the use of electronic brachytherapy. In the absence of any training protocol recommended by a recognized national professional association, the manufacturer's training protocol must be followed. The training must include, but not be limited to:

1. Device-specific radiation safety requirements;

2. Device operation;

3. Clinical use for the types of use approved by the FDA;

4. Emergency procedures, including an emergency drill; and

5. The registrant's Quality Assurance Program.

C. A registrant must retain a record of individuals receiving instruction required by §§ 5.8.13(A) and (B) of this Part in an auditable form for three (3) years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

5.8.14 Mobile Electronic Brachytherapy Service

A. A registrant providing mobile electronic brachytherapy service must, at a minimum:

1. Check each survey instrument for consistent response with a dedicated check source before medical use at each address of use or on each day of use, whichever is more restrictive. The registrant is not required to keep records of these checks.

2. Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

3. Perform, at each location on each day of use, all of the required quality assurance checks specified in § 5.8.11 of this Part to assure proper operation of the device.

5.9 Shielding and Safety Design Requirements

5.9.1 Primary and Secondary Barriers

Each therapeutic radiation machine subject to §§ 5.6, 5.7, 5.8, 5.12 or 5.13 of this Part must be provided with such primary and/or secondary barriers as are necessary to ensure compliance with §§ 1.7.1 and 1.8.1 of this Subchapter and are in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies.

5.9.2 Facility Design Information

Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of different model with a different isocenter or higher energy or workload into a room not previously approved for that energy or isocenter or planned workload must be submitted for Agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in § 5.14 of this Part.

5.10 Quality Assurance for Radiation Therapy Simulation Systems and Imaging Systems Used for Guidance During Therapeutic Radiation

A. Quality assurance for a conventional or virtual simulator and for imaging systems used for guidance during therapeutic radiation must include acceptance testing and periodic verification of system performance; and

B. Be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a

recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, must be followed.

C. Imaging systems used exclusively for simulation or guidance of therapeutic radiation must be exempt from the provisions of Part 4 of this Subchapter.

5.11 Calibration of Survey Instruments and Dosimetry Systems

5.11.1 Survey Instruments

The registrant must ensure that the survey instruments used to show compliance with this Part have been calibrated before first use, at intervals not to exceed twelve (12) months, and following repair.

5.11.2 Calibration Protocols

A. To satisfy the requirements of § 5.11.1 of this Part, the registrant must:

1. Calibrate all required scale readings up to ten (10) mSv (one thousand (1,000) mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST).

2. Calibrate at least two (2) points on each scale to be calibrated. These points should be at approximately one third (1/3) and two thirds (2/3) of full-scale.

B. To satisfy the requirements of § 5.11.2(A) of this Part, the registrant must:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent (10%).

2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty percent (20%) if a correction factor or graph is conspicuously attached to the instrument.

5.11.3 Record Retention

A. The registrant must retain a record of each calibration required in § 5.11.1 of this Part in an auditable form for three (3) years. The record must include:

1. A description of the calibration procedure; and

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

5.11.4 Use of Calibration Services

A. The registrant may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State to perform calibrations of survey instruments. Records of calibrations which contain information required by § 5.11.3 of this Part must be maintained in an auditable form by the registrant.

B. The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include: the manufacturer's name, model name, serial number, date of calibration and name of the laboratory where the calibration was performed.

5.11.5 Dosimetry Systems

A. The registrant must have a calibrated dosimetry system available for use. The system must have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration must have been performed within the previous twenty-four (24) months and after any servicing that may have affected system calibration. A system may be cross-calibrated with another system that has been calibrated in accordance with this section. This cross-calibration must have been performed within the previous twelve (12) months and after each servicing that may have affected system calibration.

1. The dosimetry system must have been calibrated at an energy (energy range) appropriate for the radiation being measured.

2. Field sizes of less than three square centimeters by three square centimeters (3 cm x 3 cm) are considered to be small and require small volume micro-detector dosimetry systems.

B. The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include: the manufacturer's name, model name, serial number, date of calibration and name of the lab where the calibration was performed.

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

5.12.1 Prohibition on Use

A. A person must 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:

1. The applicant or registrant has, at a minimum, provided the Agency with:

a. A detailed description of the device and its intended application(s);

b. Facility design requirements, including shielding and access control;

c. Documentation of appropriate training for Authorized Physician, qualified medical physicist(s) and other personnel who will be involved in performing quality assurance tasks and/or setting up patients for treatment or delivering treatment;

d. Methodology for measurement of dosages to be administered to patients or human research subjects;

e. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for machine quality assurance radiation safety;

f. Radiation safety precautions and instructions; and

g. Other information requested by the Agency in its review of the application; and

2. 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 Emerging and Future Technologies

A. Each registrant must develop, implement, and maintain a dedicated quality management program to control the processes used to administer therapeutic radiation with newly acquired, FDA-cleared emerging technologies or previously unused features of a future technology system.

B. Implementation and on-going clinical use of the emerging technology or new features must include:

1. An explicit strategy to ensure quality of processes and patient safety.

2. Approval from facility management and the radiation oncology safety team before the technology arrives and/or new features are used.

C. The quality management program must be developed by the radiation oncology safety team.

D. The quality management program must address, at a minimum:

1. Education and training about the new technology and/or features;

2. A system and timeline for on-going competency assessment of all registrant staff involved with the planning or administration of therapeutic radiation to patients or human research subjects;

3. A system for real-time recording of on-going issues related to the technology and clinical use of the new technology and/or features;

4. A strategy for timely investigation and adjudication of accidents and process deviations that may be captured in the system developed in § 5.13(B)(1) of this Part;

5. A strategy for routine review at intervals not to exceed thirteen (13) months of the clinical use of the new technology and/or features which includes an assessment of the current use compared to § 5.13(B) of this Part and plan to either update the clinical use plan or steps to bring the clinical use back into alignment with § 5.13(B) of this Part;

6. A strategy to ensure quality of equipment functions;

7. An explicit strategy for ensuring quality after hardware and software updates and after equipment repair.

E. The quality management program must be in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocol must be followed.

F. New technology issues should be reported through the vendor/manufacturer, applicable regulatory agency alerts, and/or customer service bulletins and be reviewed and addressed via a documented reporting system.

5.14 Information on Radiation Shielding Required for Plan Reviews

5.14.1 All Therapeutic Radiation Machines

A. Basic facility information including:

1. Name, telephone number and Agency registration number of the individual responsible for preparation of the shielding plan;

2. Name and telephone number of the facility supervisor; and

3. The street address, including room number, of the therapeutic radiation machine facility.

4. 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 must have primary barriers.

C. Secondary barriers must be provided in all wall, floor, and ceiling areas not having primary barriers.

5.14.2 Therapeutic Radiation Machines Up To 150 kV (Photons Only)

A. In addition to the requirements listed in § 5.14.1 of this Part, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to one hundred fifty (150) kV must submit shielding designs which contain, as a minimum, the following additional information:

1. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

2. Maximum design workload for the facility including total weekly radiation output, [expressed in gray or air kerma at one (1) meter], total beam-on time per day or week, the average treatment time per patient/human research subject, along with the anticipated number of patients to be treated per day or week.

3. A facility blueprint/drawing indicating:

a. Scale [one quarter inch (0.25”) = one foot (1’) is typical];

b. Direction of North;

c. Normal location of the therapeutic radiation machine's radiation port(s);

d. The port's travel and traverse limits;

e. General direction(s) of the useful beam;

f. Locations of any windows and doors;

g. The location of the therapeutic radiation machine control panel; and

h. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth must be noted on the plan and the operator's station at the control panel must be behind a protective barrier sufficient to ensure compliance with § 1.7.1 of this Subchapter.

4. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

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

6. The calculations which show the methodology used to determine the amount of shielding required for each physical condition [i.e., primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)] and shielding material in the facility.

    a. If commercial software is used to generate shielding requirements, the software and the version/revision date used must be identified.

    b. If the software used to generate shielding requirements is not in the open literature, an explanation of the calculations used to verify the results obtained with the software must also be submitted.

5.14.3 Therapeutic Radiation Machines Over 150 kV

A. In addition to the requirements listed in § 5.14.2 of this Part, therapeutic radiation machine facilities which produce photons with a maximum energy in excess of one hundred fifty (150) kV and/or electrons must submit shielding designs which contain, at a minimum, the following additional information:

1. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray at the isocenter and the energy(s) and type(s) of radiation produced [i.e., photon, electron]. The target to isocenter distance must be specified.

2. Maximum design workload for the facility including total weekly radiation output [expressed in gray at one (1) meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

3. Facility blueprint/drawing (including both floor plan and elevation views) indicating:

    a. Relative orientation of the therapeutic radiation machine;

    b. Scale [one quarter inch (0.25”) = one foot (1’) is typical];

    c. Type(s), thickness and minimum density of shielding material(s);

    d. Direction of North;

e. The locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

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

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

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

7. The calculations which shows the methodology used to determine the amount of shielding required for each physical condition [i.e., primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility.

a. If commercial software is used to generate shielding requirements, the software and the version/revision date used must be identified.

b. If the software used to generate shielding requirements is not in the open literature, an explanation of the calculations used to verify the results obtained with the software must also be submitted.

5.14.4 Neutron Shielding

A. In addition to the requirements listed in § 5.14.3 of this Part, therapeutic radiation machine facilities which are capable of operating at greater to or equal to ten (10) MV must submit shielding plans which contain, as a minimum, the following additional information:

1. The structural composition, thickness, minimum density and location of all neutron shielding material.

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

3. At least one (1) example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical

condition [i.e., restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility.

a. If commercial software is used to generate shielding requirements, the software and version/revision date used must be identified.

b. If the software used to generate shielding requirements is not in the open literature an explanation of the calculations used to verify the results obtained with the software must also be submitted.

4. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

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TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 40 - PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 - RADIATION

PART 5 - THERAPEUTIC RADIATION MACHINES (216-RICR-40-20-5)

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