RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: Therapeutic Radiation Machines (216-RICR-40-20-5)

Rule Identifier: 216-RICR-40-20-5

Rulemaking Action: Proposed Amendment

Important Dates:

Date of Public Notice: January 24, 2022

Hearing Date: February 7, 2022

End of Public Comment: February 23, 2022

Rulemaking Authority:

R.I. Gen. Laws § 23-1.3-5

Summary of Rulemaking Action:

This is a technical revision to synchronize wording with equivalent requirements in 10 C.F.R. §§ 35.642, 3045 & 3047 and to correct several internal cross references.

Additional Information and Public Comments:

All interested parties are invited to request additional information or submit written or oral comments concerning the proposed amendment until February 23, 2022 by contacting the appropriate party at the address listed below:

Paula Pullano

Department of Health

3 Capitol Hill

Room 410

Providence, RI 02908-5097

Paula.Pullano@health.ri.gov

Public Hearing:

A public hearing, in accordance with R.I. Gen. Laws § 42-35-2.5, to consider the proposed amendment shall be held at which time and place all persons interested therein will be heard. This hearing is subject to R.I. Gen. Laws Chapter 42-46, Open Meetings.

Public Hearing Information:

Date: February 7, 2022

Time: 10:00 A.M.

Location: Zoom Link to Come Providence, RI, 02908

The place of the public hearing is accessible to individuals with disabilities. If communication assistance (readers/interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-3395 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting. For questions regarding available parking, please contact the agency staffperson listed above.

Regulatory Analysis Summary and Supporting Documentation:

In development of this rule, consideration was given to:
1)Alternative approaches;

2)Overlap or duplication with other statutory and regulatory provisions; and

3)Significant economic impact on small business
No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.

For full regulatory analysis or supporting documentation contact the agency staffperson listed above.

STATE OF RHODE ISLAND
RHODE ISLAND DEPARTMENT OF HEALTH
CONCISE STATEMENT OF PROPOSED NON-TECHNICAL AMENDMENTS
(AMENDMENTS TO AN EXISTING REGULATION)

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-1.7(b)(8), the following is a concise statement of proposed non-technical amendments to Part 1, Part 2, Part 3, Part 4, Part 5, Part 6, Part 7, Part 8, Part 9, Part 10, Part 11, Part 12, Part 13 and Part 15 of 216-RICR-40-20, *Radiation*.

Regulation	**Rationale/Summary of Change**
§ 1.2 (A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 20
§ 2.2 (A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 19
§ 3.10(A)(4)	Revised to require submission of RCA Form 2579 in lieu of an equivalent USFDA form which is being phased out.
§ 3.13(C)(1)(c)	Corrects internal cross reference to another section in Part 3
§ 3.13(D)	Corrects internal cross reference to another section in Part 3
§ 3.14(C)	Corrects internal cross reference to another section in Part 3
§ 3.14(D)(1)	Corrects internal cross reference to another section in Part 3
Part 4 (Title)	Title of this Part has been revised to reflect the incorporation of additional requirements regarding fluoroscopically guided interventional procedures. All changes to Part 4 implement the most current revisions to Part F of the Suggested State Regulations for the Control of Radiation (SSRCR) published by the Conference of Radiation Control Program Directors, Inc. (CRCPD).
§ 4.1(B)	Clarifies that use of X-ray equipment must be under the supervision of an individual authorized by and licensed in accordance with applicable provisions of the R.I. Gen. Laws to engage in the healing arts or veterinary medicine
§ 4.1(C) &(D)	Deleted and consolidated with § 4.1(B).
§ 4.1.1(B) &(C)	Added to incorporate two additional documents by reference
§ 4.2(A)(30)	Corrects a spelling error
§ 4.2(A)(92)	"Protective garment" replaces "protective apron" for consistency with other changes
§ 4.3.1(A) and (B)	Specifies that administrative controls must include an effective radiation safety program.
§ 4.3.1(C) to (G)	Reflects the incorporation of additional administrative controls specified in the most current revision to Part F of the SSRCR.
§ 4.3.2(A)	Language added to allow limited operation of noncompliant X-ray equipment after review by a Qualified Medical Physicist

Regulation	Rationale/Summary of Change
§ 4.3.3(C) to (F)	Clarifies required training that must be completed before an individual is allowed to operate fluoroscopic X-ray equipment.
§ 4.3.3(H)	Clarifies required training that must be completed before an individual is allowed to operate dental X-ray equipment.
§ 4.3.4(A)	Clarifies information that has to be readily available to an operator of an X-ray system.
§ 4.3.6(A)	Clarifies safety precautions for individuals (other than patient) who are in the room where an X-ray is being taken.
§ 4.3.7	Deleted to address changes in "best practices".
§ 4.3.9	Clarifies safety precautions when a patient or image receptor must be provided with auxiliary support while an X-ray is being taken.
§ 4.3.10(D)	Deleted and consolidated with other Quality Control requirements in § 4.10.1
§ 4.3.10(E) and (G)	Language revised to reflect the most current revision to Part F of the SSRCR.
§ 4.3.10(F), (H) and (I)	Deleted to reflect the most current revisions to Part F of the SSRCR.
§ 4.3.10(J) and (K)	Language added to reflect the most current revisions to Part F of the SSRCR.
§ 4.3.13	Clarifies retention period for maintenance records and associated information
§ 4.3.14(A)(4)	Removes text which refers to a deleted section.
§ 4.3.14(D)	Clarifies record retention requirements for veterinary X-ray facilities
§ 4.3.15(C)	Language revised to synchronize wording with equivalent requirements in § 5.3.12(E)(1)(b) and 10 C.F.R. 35.3047
§ 4.4.3	Revised to reflect different labeling requirements for systems manufactured before 10 June 2006
§ 4.4.7	Deletes information on dental X-ray systems which has been moved to § 4.14
§ 4.4.10	Clarifies requirements regarding technique factors and kVp accuracy
§ 4.4.13	Clarifies requirements regarding use of calibrated dosimetry systems
§ 4.4.14(F)	Requires information pertaining to a radiation medical event be maintained as part of a patient's permanent medical record
§ 4.5.2	Language revised for consistency with other sections of this Part
§ 4.5.3	Clarifies training required before an individual can operate fluoroscopy equipment
§ 4.5.6	Language revised for consistency with other sections of this Part
§ 4.5.7	Language revised to reflect the most current revisions to Part F of the SSRCR.
§ 4.5.11	Deleted to reflect the most current revisions to Part F of the SSRCR.

Regulation	Rationale/Summary of Change
§ 4.5.12	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.5.13	Language added to reflect the most current revisions to Part F of the SSRCR regarding fluoroscopically-guided interventional (FGI) procedures.
§ 4.5.14(B)	Language revised to correct internal cross-reference
§ 4.5.16	Language revised for consistency with other sections of this Part
§ 4.6.1	Clarifies applicability of section to various types of X-ray systems
§ 4.6.2(C)(3)	Language revised to correct internal cross-reference
§ 4.6.2(D)	Clarifies operator protection requirements for veterinary X-ray systems
§ 4.6.3(A)	Removes language that is duplicated in another part of the regulations
§ 4.6.3(C)(4)	Language revised to correct internal cross-reference
§ 4.6.4(G)	Requires use of manual collimation standards when PBL is disabled
§ 4.6.5	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.6.6	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.6.9	Removes language that is duplicated in another part of the regulations
§ 4.6.11	Removes requirement that is superseded by MQSA standards in § 4.8
§4.6.12(A)(3)	Language deleted to reflect the most current revisions to Part F of the SSRCR
§ 4.6.14	Language revised to reflect the most current revisions to Part F of the SSRCR
§4.6.15(A)	Removes requirement that is now included in § 4.14
§4.6.15(C)	Removes requirement that is superseded by MQSA standards in § 4.8
§4.7.1(A)	Language added to reflect the most current revisions to Part F of the SSRCR
§4.7.1(F)&(G)	Language deleted to reflect the most current revisions to Part F of the SSRCR
§ 4.7.3	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.7.5	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.6	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.7	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.8	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.9	Language revised to reflect the most current revisions to Part F of the SSRCR

Regulation	Rationale/Summary of Change
§ 4.10	Language revised to consolidate QA/QC requirements in a single section to reflect the most current revisions to Part F of the SSRCR
§ 4.13	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.14	New section added to consolidate all dental X-ray system requirements in a single section to reflect the most current revisions to Part F of the SSRCR
§ 5.3.12(E)(1)(b)	Synchronize wording with equivalent requirements in 10 C.F.R. 35.3045
§ 5.4.2(A)(4)	Language revised to remove obsolete cross-reference to another section of this Subpart
§ 5.4.4	Language added to clarify that "records" refers to "records of surveys"
§§ 5.5.2 & 5.5.3	Synchronize wording with equivalent requirements in 10 C.F.R. 35.3047
§ 5.6.17(F)	Review interval revised to synchronize with equivalent requirements in 10 C.F.R. 35.642
§ 5.6.18(A)	Corrects internal cross-reference to another section of this Part
§ 5.7.1	Corrects internal cross-reference to another section of this Part
§ 5.7.4(B)	Corrects internal cross-reference to another section of this Part
§§ 5.11.11(D) & (H)	Corrects internal cross-references to other sections of this Part
§§ 6.5(D)(1) & (D)(2)	Corrects internal cross-references to other sections of this Part
§ 6.6(A)(1)	Corrects internal cross-reference to another section of this Subchapter
§ 7.2.1(A)	Revises incorporate on by reference date to 2021 to capture updates to 10 C.F.R. § 30.34 published in the Federal Register [83 FR 33046]. This C.F.R. section is already incorporated by reference in § 7.6.3
§ 7.2.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 31
§ 7.2.3(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. § 32.72 published in the Federal Register [83 FR 33046 & 83 FR 57231]. This C.F.R. section is already incorporated by reference in §§ 7.6.3 and 7.6.16(A).
§ 7.2.3(B)	Corrects typo regarding portions of 10 C.F.R Part 32 that are not being incorporated by reference.
§ 7.2.4(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 33
§ 7.2.5(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 40
§ 7.2.5(B)	Corrects typo regarding portions of 10 C.F.R Part 40 that are not being incorporated by reference.
§ 7.2.6(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 70

Regulation	Rationale/Summary of Change
§ 7.2.6(C)	Incorporates the provisions of 10 C.F.R. § 150.11(b) by reference.
§ 7.4.10	Revises wording for consistency with U.S. Nuclear Regulatory Commission usage.
§ 7.6.7(B)	Language added to further clarify when a license amendment is required
§ 7.6.8	Revise language to remove duplicate reference
§ 7.6.13	Revises paragraph numbering for consistency with other sections in this Part
§ 8.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 37 published in the Federal Register [83 FR 57231]. These 10 C.F.R. Part 37 sections are already incorporated by reference in §§ 8.6.4 and 8.6.6.
§ 8.4.4(B)	Updates mailing address
§ 8.5.9	Adds a specific incorporation by reference citation for reporting of certain events
§ 9.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 35 published in the Federal Register [83 FR 33046, 85 FR 33527 and 85 FR 44685]. These 10 C.F.R. Part 35 sections are already incorporated by reference in §§ 9.3, 9.4.7, 9.5.5, 9.5.10, 9.5.11(A), 9.5.12(A), 9.5.13(A), 9.5.18, 9.6.4, 9.7.2, 9.7.4(A), 9.7.5, 9.8.1, 9.8.4, 9.8.5, 9.8.6, 9.8.7, 9.9.1, 9.9.7, 9.9.9, 9.9.10, 9.10.1, 9.10.2, 9.11.1, 9.11.4, 9.11.15, and 9.11.17.
§ 9.2(B)	Identifies 10 C.F.R. Part 35 amendments published in the Federal Register [83 FR 33046] which are not incorporated by reference.
§ 9.4.3(B)(2)	Implements 83 FR 33046 requirements for training & qualifications of Associate Radiation Safety Officer and Ophthalmic Physicist as part of a radioactive materials license application.
§ 9.4.3(B)(4)	Corrects internal cross-reference to another section of this Subchapter
§ 9.4.5(A)(2)	Clarifies utilization of a Visiting Ophthalmic Physicist without requiring a radioactive materials license amendment [related to 83 FR 33046 amendments].
§ 9.4.5(A)(9) and (A)(10)	Implements 83 FR 33046 requirements for obtaining a radioactive materials license amendment prior to performing certain specified activities.
§ 9.4.6(A)(1) (A)(5) & (A)(6)	Implements 83 FR 33046 requirements for certain notifications that must be submitted to the RI Radiation Control Agency.
§ 9.5.1(A)(2)	Implements a requirement for written management approval to utilize a Visiting Ophthalmic Physicist [related to 83 FR 33046 amendments].
§ 9.5.1(B)	Implements 83 FR 33046 requirements for approval of Associate Radiation Safety Officer.
§ 9.5.1(C)	Eliminates unnecessary language [related to 83 FR 33046 amendments].
§ 9.5.1(K)	Implements 83 FR 33046 recordkeeping requirements for approval of Associate Radiation Safety Officer.

Regulation	Rationale/Summary of Change
§ 9.5.4(B)(5)	Implements 83 FR 33046 requirements regarding the contents of a written directive for permanent implant brachytherapy.
§ 9.5.4(B)(6)	Renumbers current § 9.5.4(B)(5) as § 9.5.4(B)(6)
§ 9.5.6 and § 9.5.6(D)	Clarifies utilization of a Visiting Ophthalmic Physicist [related to 83 FR 33046 amendments] and corrects internal cross-reference to other section of this Part
§ 9.5.6(E) & (F)	Renumbers current § 9.5.6(D) and (E) as § 9.5.4(E) and (F) respectively.
§ 9.5.9(A)	Implements 83 FR 33046 requirements regarding the definition of a misadministration.
§ 9.5.9(G)(3)	Implements 85 FR 33527and 85 FR 44685 requirements regarding the use of a social security number to identify an individual in a misadministration report.
§ 9.5.10	Implements 83 FR 33046 requirements regarding training for an Associate Radiation Safety Officer.
§ 9.5.11(B)	Corrects internal cross-reference to another section of this Subchapter
§ 9.5.16(F)(1)	Corrects internal cross-reference to another section of this Part
§ 9.7.4(B), (C) and (D)	Implements 83 FR 33046 recordkeeping requirements regarding elution of radionuclide generators.
§ 9.11.15	Implements 83 FR 33046 requirements regarding full-inspection servicing of teletherapy and gamma stereotactic radiosurgery units.
§ 9.5.19(A)	Clarifies wording to indicate that the dose limits established in § 1.8 are being referenced
§ 9.5.19(B)	Corrects internal cross-reference to another section of this Part
§ 9.6.3(B)	Clarifies rcord maintenance requirement for consistency with § 9.6.2(B)
§ 9.6.8(F)	Clarifies wording regarding detection limit for consistency with other applicable NRC guidance
§ 9.6.8(H)	Corrects internal cross-reference to another section of this Part
§ 9.6.9(E)	Corrects internal cross-reference to another section of this Part
§ 9.7.6(D)	Corrects internal cross-reference to another section of this Subchapter
§ 9.11.6(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.6(A)
§ 9.11.7(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.7(A)
§ 9.11.8(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.8(A)
§ 9.11.9(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.9(A)
§ 9.11.15(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.15(A)
§ 9.12.1	Header is removed and contents of section are collapsed into § 9.12

Regulation	Rationale/Summary of Change
§ 10.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 34 published in the Federal Register [85 FR 15347]. These 10 C.F.R. Part 34 sections are already incorporated by reference in §§ 10.6.6 and 10.7.7.
§ 10.6.3(C) (2)	Corrects internal cross-reference to another section of this Part
§ 10.6.3(C) (4)	Corrects internal cross-reference to another section of this Part
§ 10.6.3(H)	Corrects internal cross-reference to another section of this Part
§ 10.7.1(A) (7), (8) & (9)	Corrects internal cross-references to other sections of this Part
§ 10.7.10(A)	Corrects internal cross-reference to another section of this Part
§ 10.7.2(A)(9)	Corrects internal cross-reference to another section of this Part
§ 10.7.3(A)(2)	Corrects internal cross-reference to another section of this Part
§ 11.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 39 published in the Federal Register [85 FR 15347]. This 10 C.F.R. Part 39 section is already incorporated by reference in § 11.6.3.
§ 11.7.2(A)(9)	Corrects internal cross-reference to another section of this Part
§ 11.7.3(A)(2)	Corrects internal cross-reference to another section of this Part
§ 12.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. § 71.97 published in the Federal Register [83 FR 57231]. This C.F.R. section is already incorporated by reference in § 12.8.9.
§ 12.2(B)	Revises incorporation by reference date to 2021 to capture updates to 39 C.F.R. § 111.1
§ 12.2(C)	Identifies an additional subsection of 71 C.F.R. 101 that is not incorporated by reference
§ 12.8.8	Corrects section title for consistency with 10 C.F.R. 71.95
§ 12.9.1	Clarifies that RCA and not NRC is responsible for certificate approval.
§ 13.4.7(A) & (B)	Corrects internal cross-references to another section of this Subchapter
§ 15.5.7(C) (11)(c)	Language added to clarify that Category 3K also includes all other use of unsealed radioactive material not authorized for commercial distribution.

216-RICR-40-20-5

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 shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience 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 shall, 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 shall, 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 § 5.11 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 shall be directed to the Agency using contact information specified in § 1.4 of this Subchapter.

5.1.2 Incorporation by Reference

A. This Part hereby adopts and incorporates 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 this Part.

B. This Part hereby adopts and incorporates 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 this Part.

C. This Part hereby adopts and incorporates 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 this Part.

D. This Part hereby adopts and incorporates 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 this Part.

5.2 Definitions

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

1. “Absorbed dose (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 SI unit of absorbed dose is joule per kilogram and the name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

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

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

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

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

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

7. “Air kerma (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).

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

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

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

11. “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.

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

13. “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.

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

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

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

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

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

19. “Dose equivalent (HT)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the Sievert (Sv) and rem.

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

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

22. “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.

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

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

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

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

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

28. “Gray (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) is being replaced by the gray. [one (1) Gy = one hundred (100) rad].

29. “Half-value layer (HVL)" 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 half (1/2) of the value measured without the material at the same point.

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

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

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

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

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

35. “Kilo electron volt (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.

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

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

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

39. “mA” means milliampere.

40. “Mega electron volt (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.

41. "Mobile electronic brachytherapy service" means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

42. "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 arc, skip, conformal, intensity modulation and rotational therapy.

43. "Nominal treatment distance" means:

    a. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

    b. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

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

45. "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

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

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

48. "Practical range of electrons" means the classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays.

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. “Radiation field” (See "Useful beam")

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. “Radiation detector” means a device which, 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.

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

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

56. “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.

57. “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.

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

59. “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.

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

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

62. “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.

63. “Sievert (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].

64. “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.

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

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

67. “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.

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

69. “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.

70. “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.

71. “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.

72. “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.

73. “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 shall also be considered therapeutic radiation machines.

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

75. “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.

76. “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.

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

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

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

80. “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.

81. “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 shall 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 shall 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 shall not be used for irradiation of patients/human research subjects.

5.3.3 Training for Therapeutic Radiation Machine Authorized Users

A. The registrant for any therapeutic radiation machine subject to §§ 5.6 or 5.7 of this Part shall require the Authorized User to be a physician who:

1. Is certified in:

   a. Radiation oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or

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

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

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

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

   a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

      (1) Radiation physics and instrumentation;

      (2) Radiation protection;

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

      (4) Radiation biology.

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

      (1) Review of the full calibration measurements and periodic quality assurance checks;

      (2) Evaluation of prepared treatment plans and calculation of treatment times and patient/human research subject treatment settings;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

c. To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an Authorized User. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the therapeutic radiation machine doses and collaborating with the Authorized User in the review of patients'/human research subjects' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients'/human research subjects' reaction to radiation; and

(4) Post-administration follow-up and review of case histories.

3. Notwithstanding the requirements of §§ 5.3.3(A)(1) and (2) of this Part, the registrant for any therapeutic radiation machine subject to § 5.6 of this Part may also submit the training of the prospective Authorized User physician for Agency review on a case-by-case basis.

4. A physician shall not act as an Authorized User for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Agency.

5.3.4 Training for Qualified Medical Physicist

A. The registrant for any therapeutic radiation machine subject to §§ 5.6 or 5.7 of this Part shall 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 radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

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

   a. Therapeutic radiological physics; or

   b. Roentgen-ray and gamma-ray physics; or

   c. X-ray and radium physics; or

   d. Radiological physics; or

   e. Therapeutic medical physics; or

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

4. Be 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 shall 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 shall be kept on file at the facility. Information on former operators shall 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 and Rules shall be developed by a Qualified Medical Physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these Rules.

5.3.7 Exposure Prohibited

Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic

radiation machine Authorized User. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

5.3.8 Visiting Authorized User

A. Notwithstanding the provisions of § 5.3.3(A)(4) of this Part, a registrant may permit any physician to act as a Visiting Authorized User under the term of the registrant's Certificate of Registration for up to sixty (60) days per calendar year under the following conditions:

1. The Visiting Authorized User 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 User meets the requirements established for Authorized User(s) in §§ 5.3.3(A)(1) and (2) of this Part; and

3. The registrant shall maintain copies of the written permission required in § 5.3.8(A)(1) of this Part and documentation that the Visiting Authorized User 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 shall be instructed in and shall comply with the provisions of the registrant's 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 shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:

1. Report of acceptance testing.

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

4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

5.3.11 Records Retention

All records required by this Part shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in this Part. All required records shall be retained 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 microfilmed or otherwise 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 shall 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 ~~referring~~ prescribing physician.

1. A registrant shall report any dose to a nursing child that is a result of an administration of radiation to a breast-feeding individual that is greater than fifty (50) mSv (five (5) rem) total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

B. The registrant shall notify the Agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in §§ 5.3.12(A) or (A)(1) of this Part.

C. The registrant shall submit a written report to the Agency within fifteen (15) days after discovery of a dose to the embryo/fetus or nursing child that requires a report in §§ 5.3.12(A) or (A)(1) of this Part.

1. The written report ~~shall~~ must include:

a. The registrant's name and registration number;

b. The name of the ~~referring~~ prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

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

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 ~~pregnant individual's~~ mother's or child'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 or child.

D. The registrant shall 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) or (A)(1) of this Part, unless the referring physician personally informs the registrant either that he or she will inform the ~~pregnant individual~~ mother or that, based on medical judgment, telling the ~~pregnant individual~~ mother would be harmful. The registrant is not required to notify the ~~pregnant individual~~ mother without first consulting with the referring physician. If the referring physician or ~~pregnant individual~~ mother cannot be reached within twenty-four (24) hours, the registrant shall make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the embryo/fetus or for the nursing child, 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 ~~pregnant individual's~~ mother's or child's responsible relative or guardian instead of the ~~pregnant individual~~ mother. If an oral notification is made, the registrant shall inform the ~~pregnant individual~~ mother, or the ~~pregnant individual's~~ 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 shall provide such a written description if requested.

E. A registrant shall:

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

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

b. Identification number or if no other identification number is available, the social security number ~~or other identification number, if one has been assigned,~~ of the pregnant individual or the nursing child who is the subject of the event; and

2. ~~c.~~ 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 Protection Surveys

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

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in § 1.7.1(A) of this Subchapter; and

2. Radiation levels in unrestricted areas do not exceed the limits specified in §§ 1.8.1(A) and (B) of this Subchapter.

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

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

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

3. After relocating the therapeutic radiation machine; 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.

C. The survey record shall indicate all instances where the facility, in the opinion of the Qualified Medical Physicist or a Certified Health Physicist, is in violation of applicable regulations. The survey record shall 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, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

D. 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 shall 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 shall:

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 ~~under § 1.8.1(C) of this Subchapter~~ that authorizes radiation levels in unrestricted areas greater than those permitted by §§ 1.8.1(A) and (B) of this Subchapter.

5.4.3 Dosimetry Equipment

A. The registrant shall have a calibrated dosimetry system available for use. The system shall 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 shall have been performed within the previous twenty-four (24) months and after any servicing that may have affected system calibration.

1. For beams with energies greater than one (1) MV (one (1) MeV), the dosimetry system shall have been calibrated for Cobalt-60;

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

B. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with § 5.4.3(A) of this Part. This comparison shall have been performed within the previous twelve (12) months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in § 5.4.3(A) of this Part.

C. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by §§ 5.4.3(A) and 5.4.3(B) of this Part, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Qualified Medical Physicist.

5.4.4 Reports of External Beam Radiation Therapy Surveys and Measurements

The registrant for any therapeutic radiation machine subject to §§ 5.6 or 5.7 of this Part shall 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 (30) 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 User. The quality management program shall address, as a minimum, the following specific objectives:

1. Written Directive

   a. A written directive must be dated and signed by an Authorized User 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 shall 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 User within forty-eight (48) hours of the oral revision;

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

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

e. The registrant shall retain a copy of each written directive, in an auditable form, for three (3) years after the date of administration.

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

a. Prior to the administration of each course 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 both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive; and

(2) Verifying that any manual and computer-generated calculations are correctly transferred into the consoles of therapeutic radiation machines;

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

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

3. A registrant shall 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 Reports and Notifications of Misadministrations

A. A registrant shall report any event resulting from intervention by a patient or human research subject in which the administration of therapeutic radiation

machine radiation results, or will result in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

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

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

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than five one hundredths (0.05) Sv (five (5) rem) effective dose equivalent, one half (0.5) Sv (fifty (50) rem) to an organ or tissue, or one half (0.5) Sv (fifty (50) rem) shallow dose equivalent to the skin; and

   a. The total dose delivered differs from the prescribed dose by twenty percent (20%) or more;

   b. The total dosage delivered differs from the prescribed dosage by twenty percent (20%) or more or falls outside the prescribed dosage range; or

   c. The fractionated dose delivered differs from the prescribed dose for a single fraction, by fifty percent (50%) or more.

~~2. The calculated weekly administered dose differs from the weekly prescribed dose by more than thirty percent (30%); or~~

2. A dose that exceeds five one hundredths (0.05) Sv (five (5) rem) effective dose equivalent, one half (0.5) Sv (fifty (50) rem) to an organ or tissue, or one half (0.5) Sv (fifty (50) rem) shallow dose equivalent to the skin from any of the following:

   a. An administration of a dose or dosage to the wrong individual or human research subject; or

   b. An administration of a dose or dosage delivered by the wrong mode of treatment.

~~3. The calculated total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose;~~

3, A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

   a. One half (0.5) Sv (fifty (50) rem) or more the expected dose to that site from the procedure if the administration had been given in

accordance with the written directive prepared or revised before administration; and

b. Fifty percent (50%) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

C. The registrant shall notify the Agency by telephone no later than the next calendar day after discovery of the misadministration.

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

D. The registrant shall submit a written report to the Agency within fifteen (15) days after discovery of the misadministration. The written report shall 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 individuals(s) who received the misadministration;

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.~~; and~~

~~8. If there was notification, what information was provided to the individual.~~

E. The report shall not contain the individual's name or any other information that could lead to the identification of the individual. ~~To meet the requirements of this Section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.~~

F. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be

reached within twenty-four (24) hours, the registrant shall notify the individual as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

G. To meet the requirements of § 5.5.2~~(B)(1)~~ of this Part, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If an oral notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that ~~either a copy of the report that was submitted to the Agency, or~~ a written description of ~~both~~ the event ~~and the consequences as they may affect them~~ can be obtained from the registrant upon request. The registrant shall 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 misadministration, or to that individual's responsible relatives or guardians.

I. The registrant shall retain a record of a misadministration in accordance with § 5.5.3 of this Part. ~~A copy of the record required shall be provided to the referring physician if other than the registrant within fifteen (15) days after discovery of the misadministration.~~

5.5.3 Records of Misadministrations

A. A registrant shall retain a record of misadministrations reported in accordance with § 5.5.2 of this Part for three (3) years. ~~The record shall contain the following~~ The registrant shall annotate a copy of the report provided to the Agency with:

1. The ~~registrant's name and the names of the individuals involved (including the prescribing physician, allied health personnel~~, name of the individual who ~~received~~ is the subject of the misadministration~~, and the individual's referring physician, if applicable)~~; and

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

~~3. A brief description of the event; why it occurred; the effect, if any, on the individual;~~

~~4. The actions, if any, taken or planned to prevent recurrence; and~~

~~5. Whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.~~

B. A registrant shall provide a copy of the annotated report to the referring physician, if other than the registrant, no later than fifteen (15) days after discovery of the misadministration.

5.5.4 Implementation of Quality Management Program

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

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, all recordable events, and all misadministrations 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 Follow-up Required for Recordable Event

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

1. Assembling the relevant facts including the cause;

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

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

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

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 shall 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 shall not exceed one (1) mGy (one hundred (100) mrad) in any one (1) hour.

2. > 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 shall not exceed one (1) cGy (one (1) rad) 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 shall not exceed thirty (30) cGy (thirty (30) rad) per hour.

3. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in §§ 5.6.1(A)(1) and 5.6.1(A)(2) of this Part for the specified operating conditions. Records on leakage radiation measurements shall be maintained 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 shall 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 shall 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 shall be indicated by a light beam.

5.6.4 Filter System

A. The filter system shall be so designed that:

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

2. For equipment installed after August 1, 1978, an interlock system prevents irradiation if the proper filter is not in place;

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

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

5.6.5 Tube Immobilization

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

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

5.6.6 Source Marking

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

5.6.7 Beam Block

Contact therapy tube housing assemblies shall 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 shall be provided to terminate the irradiation after a pre-set time interval.

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

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

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

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

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

G. The timer shall 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 shall 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, shall have:

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

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

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

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

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

6. For therapeutic radiation machines manufactured after August 1, 1978, 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 shall be possible to activate only one (1) X-ray tube at any time;

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

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

5.6.11 Target-to-Skin Distance (TSD)

There shall 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 shall 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 shall be controlled by the operator from the control panel. An indication of shutter position shall 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 shall be clearly labeled as such upon the tube housing assembly and shall 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~~ § 5.9.1 of this Part, the treatment room shall meet the following design requirements:

1. Aural Communication. Provision shall 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 shall be made to permit continuous observation of the patient/human research subject during irradiation and the viewing system shall be so located that the operator can observe the patient/human research subject from the control panel. The therapeutic radiation machine shall 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 shall meet the following additional requirements:

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

2. The control panel shall be located outside the treatment room.

3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and 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 shall be reduced to less than one (1) mGy (one hundred (100) mrad) per hour.

5.6.16 Full Calibration Measurements

A. Full calibration of a therapeutic radiation machine subject to § 5.6 of this Part shall be performed by, or under the direct supervision of, a Qualified Medical Physicist:

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

2. At intervals not exceeding twelve (12) calendar months; and

3. Before medical use under the following conditions:

a. 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

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

4. Notwithstanding the requirements of § 5.6.16(A)(3) 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 shall 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)(3)(a) of this Part.

B. To satisfy the requirement of § 5.6.16(A) of this Part, full calibration shall include all measurements recommended for annual calibration by "AAPM Protocol for 40-300 kV X-ray Beam Dosimetry in Radiotherapy and Radiobiology": AAPM Report No. 76, prepared by AAPM Radiation Therapy Committee Task Group #61.

C. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for 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 Periodic Quality Assurance Checks

A. Periodic quality assurance checks shall 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, quality assurance checks shall meet the following requirements:

1. The registrant shall perform quality assurance checks in accordance with written procedures established by the Qualified Medical Physicist; and

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in § 5.6.16(A) of this Part. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in § 5.6.16(A) of this Part, shall be stated.

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

D. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Qualified Medical Physicist's quality assurance check procedures, those elements of a full calibration shall be performed, as required in § 5.6.16(A) of this Part, that are necessary to determine that all affected parameters are within acceptable limits. Other quality assurance check procedures should be repeated, as necessary, to ensure that all system parameters are within acceptable limits.

E. The registrant shall use the dosimetry system described in § 5.4.3(B) of this Part to make the quality assurance check required in § 5.6.17(B) of this Part.

F. The registrant shall have the Qualified Medical Physicist review and sign the results of each radiation output quality assurance check within ~~thirty (30)~~ fifteen (15) days of the date that the check was performed.

G. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to § 5.6 of this Part are performed at intervals not to exceed thirty (30) days.

H. Notwithstanding the requirements of §§ 5.6.17(F) and (G) of this Part, the registrant shall 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 within the thirty (30) day period immediately prior to said administration.

I. To satisfy the requirement of § 5.6.17(G) of this Part, safety quality assurance checks shall 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 systems;

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

J. The registrant shall maintain a record of each quality assurance check required by §§ 5.6.17(A) and (G) of this Part for three (3) years. The record shall 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 and serial number of the 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.

5.6.18 Operating Procedures

A. The therapeutic radiation machine shall not be used for irradiation of patients/human research subjects unless the requirements of ~~§§ 5.16 and 5.17~~ §§ 5.6.16 and 5.6.17 of this Part have been met.

B. Therapeutic radiation machines shall 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 supporting or restraining devices shall be used.

D. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed fifty (50) kV. In such cases, the holder shall 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 shall be maintained at the therapeutic radiation machine control console; and

F. No individual other than the patient/human research subject shall 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 shall 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 shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall 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) shall be operable and calibrated in accordance with § 5.8 of this Part.

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

5.7.1 Possession of Survey Instrument(s)

Each facility location authorized to use a therapeutic radiation machine in accordance with § 5.7 of this Part shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall 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) shall be operable and calibrated in accordance with ~~§ 5.5~~ § 5.8 of this Part.

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

A. 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), shall 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 shall 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.

B. 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 shall 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 shall be averaged over an area not exceeding one hundred square centimeters (100 cm^2).

C. For equipment manufactured after July 1, 1999, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

D. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in §§ 5.7.2(A) through (C) of this Part for the specified operating conditions. Records on leakage radiation measurements shall be maintained 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 shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 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 shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

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 shall 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 shall 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 shall be made with the beam limiting devices closed and

any residual aperture blocked by at least two (2) tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters (10 cm^2);

2. Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter (1 cm^2) suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one (1) centimeter of water equivalent build up material.

5.7.4 Filters/Wedges

A. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.

B. If the absorbed dose rate information required by ~~§ 5.7.1~~ § 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 shall be removable only by the use of tools.

C. For equipment manufactured after January 1, 1985 which utilize a system of wedge filters, inter-changeable field flattening filters, or interchangeable beam scattering foils:

1. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

2. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

3. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

4. An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room 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

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

5.7.6 Beam Monitors

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

B. Equipment manufactured after January 1, 1985 shall 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 manufactured on or before January 1, 1985 shall be provided with at least one (1) radiation detector. This detector shall be incorporated into a useful beam monitoring system.

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

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

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

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

4. For equipment manufactured after January 1, 1985, the design of the beam monitoring systems shall ensure that the:

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

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

5. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after January 1, 1985, each display shall:

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 shall be retrievable in at least one system for a twenty (20) minute period of time.

5.7.7 Beam Symmetry

A. A bent-beam linear accelerator with beam flattening filter(s) subject to § 5.7 of this Part shall be provided with auxiliary device(s) to monitor beam symmetry.

B. The device(s) referenced in § 5.7.7(A) of this Part shall be able to detect field asymmetry greater than ten percent (10%); and

C. The device(s) referenced in § 5.7.7(A) of this Part shall be configured to terminate irradiation if the specifications in § 5.7.7(B) of this Part cannot be maintained.

5.7.8 Selection and Display of Dose Monitor Units

A. Irradiation shall 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 shall be displayed at the treatment control panel until reset manually for the next irradiation.

C. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

D. For equipment manufactured after January 1, 1985, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

5.7.9 Air Kerma Rate/Absorbed Dose Rate

A. For equipment manufactured after January 1, 1985, a system shall 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 shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall 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 shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four (4) Gy (four hundred (400) rad); and

4. For each therapeutic radiation machine, the registrant shall 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) shall be maintained 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 shall 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 shall 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. For equipment manufactured after January 1, 1985, an indicator on the control panel shall show which monitoring system has terminated irradiation.

5.7.11 Termination of Irradiation

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

5.7.12 Interruption of Irradiation

If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall 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 shall be automatically terminated.

5.7.13 Timer

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

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

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

D. The timer shall 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 shall meet the following additional requirements:

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

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

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

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

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

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

5.7.15 Selection of Energy

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

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

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

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

4. For equipment manufactured after July 1, 1999, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (Edition 3.1 – July 2014).

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 shall meet the following requirements:

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

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

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

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

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

a. For equipment manufactured after January 1, 1985:

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

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

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

b. For equipment manufactured after July 1, 1999:

(1) An interlock system shall 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;

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

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

7. For equipment manufactured after January 1, 1985, an interlock system shall be provided to terminate irradiation if movement:

a. Occurs during stationary beam radiation therapy; or

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

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 shall 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 shall also:

a. Be located outside the treatment room;

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

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

d. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

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

4. Aural Communications. Provision shall 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 shall 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 shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF."

6. Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

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 shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

8. Emergency Cutoff Switches. At least one (1) emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination capability required by § 5.7.11 of this Part. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

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

10. Surveys for Residual Radiation. Surveys for residual activity shall 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 shall be required in facilities having therapeutic radiation machines with energies of five hundred (500) kV and above. The Qualified Medical Physicist shall 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(E) of this Part;

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

6. Performing calculations/assessments regarding misadministrations.

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 shall 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, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes.

B. Therapeutic radiation machines shall 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, shall be secured to prevent unauthorized use.

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

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

F. A copy of the current operating and emergency procedures shall 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 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist.

B. Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47", prepared by AAPM Radiation Therapy Task Group 45, and the manufacturer's contractual specifications. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

C. Full calibration shall include measurement of all applicable parameters required by "Quality Assurance of Medical Accelerators: AAPM Report No. 142", and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47", prepared by AAPM Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding twelve (12) calendar months, unless a more frequent interval is required in AAPM Report No. 142.

1. AAPM Report 142 supersedes Table II of "Comprehensive QA for Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation Therapy Task Group 40.

D. The Qualified Medical Physicist shall perform or directly supervise 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 shall 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 shall 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).

E. The registrant shall use the dosimetry system described in § 5.4.3(A) of this Part to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in §§ 5.7.20(B), (C), and (D) of this Part may then be made using a dosimetry system that indicates relative dose rates.

F. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, 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 performance of the calibration.

G. Therapy-Related Computer Systems. The registrant shall 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 shall be followed.

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

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

b. The accuracy of dose 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 shall be evaluated and approved by the Authorized User and the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

5.7.21 Periodic Quality Assurance Checks

A. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to § 5.7 of this Part at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46, prepared by AAPM Radiation Therapy Committee Task Group 40. All periodic quality assurance checks with an annual frequency do not have to be performed at the same time, but shall be completed during an interval not to exceed twelve (12) consecutive calendar months.

B. The registrant shall use a dosimetry system which has been inter-compared within the previous twelve (12) months with the dosimetry system described in § 5.4.3(A) of this Part to make the periodic quality assurance checks required in § 5.7.21(A) of this Part.

C. The registrant shall perform periodic quality assurance checks required by § 5.7.21(A) of this Part in accordance with procedures established by the Qualified Medical Physicist.

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

1. The Authorized User or Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall 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 shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within three (3) treatment days; and

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

E. Therapeutic radiation machines subject to § 5.7 of this Part shall have the following safety quality assurance checks performed at intervals not to exceed one (1) week:

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

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

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

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

G. The registrant shall maintain a record of each quality assurance check required by §§ 5.7.21(A) and (E) of this Part for three (3) years. The record shall 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 and serial number of the 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 Quality Assurance Checks for IMRT

A. Quality assurance checks for IMRT shall:

1. Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans; and

   a. IMRT is a rapidly evolving modality and the QA program shall also evolve to handle new issues that arise. "Guidance document on delivery, treatment planning, and clinical implementation of IMRT: AAPM Report No. 82", prepared by the IMRT subcommittee of the AAPM radiation therapy committee, provides some suggestions on establishing such a QA program.

2. Be performed in accordance with the manufacturer's contractual specifications.

5.8 Calibration of Survey Instruments

5.8.1 Calibration Required

The registrant shall 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.

5.8.2 Calibration Protocols

A. To satisfy the requirements of § 5.8.1 of this Part, the registrant shall:

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

C. 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.

5.8.3 Record Retention

A. The registrant shall retain a record of each calibration required in § 5.8.1 of this Part for three (3) years. The record shall 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.

5.8.4 Use of Calibration Services

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 §§ 5.8.3 of this Part shall be maintained by the registrant.

5.9 Shielding and Safety Design Requirements

5.9.1 Primary and Secondary Barriers

Each therapeutic radiation machine subject to §§ 5.6 or 5.7 of this Part shall 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.

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 higher energy into a room not previously approved for that energy shall 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 § 5.13 of this Part.

5.10 Quality Assurance for Radiation Therapy Simulation Systems

A. Quality assurance for a conventional or virtual simulator shall include acceptance testing and periodic verification of system performance; and

B. Be performed in accordance with "Comprehensive QA for Radiation Oncology: AAPM Report No. 46", prepared by AAPM Radiation Therapy Committee Task Group 40, for a conventional simulator; or

C. Be performed in accordance with "Quality assurance for computed tomography simulators and the computed tomography-simulation process: AAPM Report No. 83", prepared by AAPM Radiation Therapy Committee Task Group 66, for a virtual simulator.

5.11 Electronic Brachytherapy

5.11.1 Applicability

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

B. An electronic brachytherapy device that does not meet the requirements of § 5.11 of this Part shall not be used for irradiation of patients.

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

5.11.2 Possession of Survey Instrument(s)

Each facility location authorized to use an electronic brachytherapy device in accordance with § 5.11 of this Part shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall 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) shall be operable and calibrated in accordance with § 5.8 of this Part for the applicable electronic brachytherapy source energy.

5.11.3 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 shall meet the following design requirements:

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

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

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

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

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

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

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

    c. When any door referred to in § 5.11.3(A)(5)(b) 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 shall be reduced to less than one (1) mGy (one hundred (100) mrad) per hour.

6. Facility design requirements for electronic brachytherapy devices which would operate in the fifty to one hundred fifty (50 – 150) kV range have intentionally been omitted because an evaluation of this technology, as it existed at the time § 5.11 of this Part was finalized, appears to indicate that such devices are not likely to be produced.

5.11.4 Electrical Safety for Electronic Brachytherapy Devices

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

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

D. Equipment manufactured after January 1, 2006 shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

1. IEC 60601-1:1998+A1+A2:1995;

2. IEC 60601-1-2:2001;

3. IEC 60601-2-8:1999; and

4. IEC 60601-2-17:2004.

5.11.5 Control Panel Functions

A. The control panel, in addition to the displays required by other provisions in § 5.11 of this Part, shall:

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

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

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

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

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

5.11.6 Timer

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

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

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

D. The timer shall 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 shall be necessary to reset the elapsed time indicator.

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

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

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

5.11.7 Qualified Medical Physicist Support

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

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

2. Generation of the necessary dosimetric information;

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

4. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in § 5.11.11 of this Part;

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

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

B. If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by § 5.11.8 of this Part shall 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.

5.11.8 Operating Procedures

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

B. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of §§ 5.4, 5.11.9 and 5.11.10 of this Part have been met;

C. The electronic brachytherapy device shall be rendered inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

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

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

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

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

2. The names and telephone numbers of the Authorized Users, 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 shall 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 shall be kept where the operator is located during electronic brachytherapy device operation.

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

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

5.11.9 Safety Precautions for Electronic Brachytherapy Devices

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

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

C. A Qualified Medical Physicist and either an Authorized User or a physician or electronic brachytherapy device operator, under the supervision of an Authorized

User, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device;

D. When shielding is required by § 5.11.3(A)(4) of this Part, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist shall 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 shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

5.11.10 Electronic Brachytherapy Source Calibration Measurements

A. Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to § 5.11 of this Part shall be performed by, or under the direct supervision of, a Qualified Medical Physicist;

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

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

D. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

1. The output within two percent (2%) of the expected value, if applicable, or determination of the output if there is no expected value;

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

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

4. Evaluation that the relative dose distribution about the source is within five percent (5%) of that expected; and

5. Source positioning accuracy to within one (1) millimeter within the applicator;

E. Calibration of the X-ray source output required by §§ 5.11.10(A) through (D) of this Part shall be in accordance with current published recommendations from a

recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.

F. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall 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 and serial numbers 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.

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

A. Quality assurance checks shall be performed on each electronic brachytherapy device subject to § 5.11 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; and

a. 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 § 5.11.14 of this Part for additional clarification.

3. After each X-ray tube installation.

B. The registrant shall perform periodic quality assurance checks required by § 5.11.11(A) of this Part in accordance with procedures established by the Qualified Medical Physicist.

C. To satisfy the requirements of § 5.11.11(A) of this Part, radiation output quality assurance checks shall include at a minimum:

1. Verification that output of the electronic brachytherapy source falls within three percent (3%) of expected values, as appropriate for the device, as determined by:

a. Output as a function of time, or

b. Output as a function of setting on a monitor chamber.

2. Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by § 5.11.10 of this Part; and

3. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one (1) mm.

D. The registrant shall use a dosimetry system that has been intercompared within the previous twelve (12) months with the dosimetry system described in ~~§ 5.3(A)~~ § 5.4.3(A) of this Part to make the quality assurance checks required in § 5.11.11(C) of this Part;

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

1. An Authorized User and Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the 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 shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within two (2) days; and

3. The Qualified Medical Physicist shall 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 § 5.11.11(A) of this Part, safety device quality assurance checks shall, 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 § 5.11.11(F) of this Part indicate any malfunction, a registrant shall 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 items.

H. The registrant shall maintain a record of each quality assurance check required by §§ 5.11.11(C) and ~~5.11.11(G)~~ 5.11.11(F) of this Part in an auditable form for three (3) years.

1. The record shall 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 § 5.11.11(C) of this Part, the record shall 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.

5.11.12 Therapy-Related Computer Systems

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

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

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

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

3. The accuracy of isodose plots and graphic displays;

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

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

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

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

5.11.13 Training

A. A registrant shall 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 § 5.11.8 of this Part. If the interval between patients exceeds one (1) year, retraining of the individuals shall 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 Users and § 5.3.4 of this Part for Qualified Medical Physicists, these individuals shall 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 shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

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

5.11.14 Mobile Electronic Brachytherapy Service

A. A registrant providing mobile electronic brachytherapy service shall, 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 § 5.11.11 of this Part to assure proper operation of the device.

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

5.12.1 Prohibition on Use

A. A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

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 User physician(s) and qualified medical physicist(s)

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 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 Information on Radiation Shielding Required for Plan Reviews

5.13.1 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 shall have primary barriers.

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

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

A. In addition to the requirements listed in § 5.13.1 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 shall submit shielding plans 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 (rad) 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 shall be noted on the plan and the operator's station at the control panel shall 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.

5.13.3 Therapeutic Radiation Machines Over 150 kV

A. In addition to the requirements listed in § 5.13.1 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 shall submit shielding plans 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 (rad) at the isocenter and the energy(s) and type(s) of radiation produced [i.e., photon, electron]. The target to isocenter distance shall be specified.

2. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) 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];, type(s);

   c. 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. 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. At least one (1) example calculation 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. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

5.13.4 Neutron Shielding

A. In addition to the requirements listed in § 5.13.3 of this Part, therapeutic radiation machine facilities which are capable of operating above ten (10) MV shall 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. If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

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