DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - PARTICLE ACCELERATORS AND THERAPEUTIC RADIATION MACHINES IN THE HEALING ARTS

6 CCR 1007-1 Part 24

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

PART 24: PARTICLE ACCELERATORS AND THERAPEUTIC RADIATION MACHINES IN THE HEALING ARTS

24.1 Purpose and Scope.

24.1.1 Authority.

24.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(l), and 25-11-104, CRS.

24.1.2 Basis and Purpose.

24.1.2.1 A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

24.1.3 Scope.

24.1.3.1 This Part 24 establishes requirements for use of particle accelerators and therapeutic radiation machines in the healing arts.

24.1.4 Applicability.

24.1.4.1 The provisions of Part 24 are in addition to, and not in substitution for, other applicable provisions in Parts 1, 2, 4, 10 or other parts of these regulations.

24.1.4.2 The requirements and provisions of this part apply to each registrant or applicant for registration subject to this part unless specifically exempted, and also apply as appropriate to an equivalent licensee or applicant for a license.

24.1.5 Published Material Incorporated by Reference.

24.1.5.1 Published material incorporated in Part 24 by reference is available in accord with Part 1, Section 1.4.

24.2 Definitions.

As used in Part 24, these terms have the definitions set forth below.

"AAPM Report 46" means "Comprehensive QA for Radiation Oncology", AAPM Report No. 46 by Task Group 40 of the Radiation Therapy Committee of the American Association of Physicists in Medicine (Medical Physics, Vol. 21, Issue 4, April 1994, pp. 581-618).

"AAPM Report 47" means "AAPM Code of Practice for Radiotherapy Accelerators", AAPM Report No. 47 by Task Group 45 of the Radiation Therapy Committee of the American Association of Physicists in Medicine (Medical Physics, Vol. 21, Issue 7, July 1994, pp. 1093-1121).

"AAPM Report 82" means "Guidance Document on Delivery, Treatment Planning, and Clinical Implementation of IMRT", AAPM Report No. 82 by the IMRT Subcommittee of the Radiation Therapy Committee of the American Association of Physicists in Medicine (Medical Physics, Vol. 30, Issue 8, August 2003, pp. 2089-2115).

"AAPM Report 83" means "Quality Assurance for Computed-Tomography Simulators and the Computed Tomography-Simulation Process", AAPM Report No. 83 by Task Group 66 of the Radiation Therapy Committee of the American Association of Physicists in Medicine (Medical Physics, Vol. 30, Issue 10, October 2003, pp. 2762-2792).

"AAPM Task Group 101 Report" means "Stereotactic Body Radiation Therapy: The report of AAPM Task Group 101", AAPM Report by Task Group 101 of the Treatment Delivery Subcommittee, of the American Association of Physicists in Medicine (Medical Physics, Vol. 37, Issue 8, August 2010, pp. 4078-4101).

"AAPM Task Group 142 Report" means "Quality Assurance of Medical Accelerators", AAPM Report by Task Group 142 of the Quality Assurance and Outcome Improvement Subcommittee of the American Association of Physicists in Medicine (Medical Physics, Vol. 36, Issue 9, September 2009, pp. 4197-4212), International Standard Book Number 9781888340884.

"AAPM Task Group 179 Report" means "Quality Assurance for Image-guided Radiation Therapy Utilizing CT-based Technologies", a report of the AAPM Task Group 179, (Medical Physics, Vol. 39, Issue 4, April 2012, pp. 1946-1963), International Standard Book Number 9781936366156.

"ADCL" means a dosimetry calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM).

"Added filtration" means addition of a filter to the inherent filtration.

"Authorized user" means an individual who meets the requirements of Part 2, Appendix 2K.

"Barrier". See "protective barrier".

"Beam axis" means, for purposes of Part 24, the axis of rotation of the beam-limiting device.

"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.

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

"Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to spread out a beam of electrons to provide a more uniform electron distribution in the useful beam.

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

"Central axis" means "beam axis".

"Changeable filter" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.

"Collimator" means, for purposes of Part 24, a physical device that constrains the ionizing radiation.

"Contact therapy system" means a therapeutic radiation machine in which an external source of radiation is a short target to skin distance (TSD), usually less than five centimeters, from the skin. Such systems are not designed for intracavitary, intraluminal or interstitial use.

"Detector". See "radiation detector".

"Direct supervision". See Part 1 definition.

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

"Electronic brachytherapy device" means the components of an electronic brachytherapy system that produce and deliver therapeutic radiation, including the x-ray tube, control mechanism, cooling system, and the power source.

"Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

"Electronic brachytherapy system" means a therapeutic radiation machine in which an x-ray source is used to irradiate tissue by intracavitary, intraluminal, interstitial, or similar application with the source in contact with, very close to, or at a distance usually less than five centimeters from the target volume

"External beam radiation therapy system" means a therapeutic radiation machine in which the source of radiation is a certain distance, usually more than five centimeters, from the body.

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

"Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 24.7.

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

"General supervision". See Part 1 definition.

"Half-value layer" (HVL) means the thickness of a specified material needed to reduce a radiation beam to one-half of its original intensity.

"Image Guided Radiation Therapy" (IGRT) is the process which uses ionizing radiation for frequent two or three-dimensional imaging during a course of radiation treatment, to direct radiation therapy utilizing the imaging coordinates of the actual radiation treatment plan.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the housing assembly.

"Intensity Modulated Radiation Therapy" (IMRT) means radiation therapy using highly modulated spatially non-uniform radiation beam intensities that have been determined by computer-based optimization techniques.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

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

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry and collimator move through their full range of motion.

"Lead equivalent" means the thickness of a material that provides the same attenuation, under specified conditions, as lead.

"Leakage radiation" means the portion of ionizing radiation originating from the radiation therapy system that is not part of the useful beam. See "useful beam".

"Light field" means the area illuminated by light, simulating the radiation field.

"Misadministration". See "reportable medical event".

"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.

"Monitor unit" (MU). See "dose monitor unit".

"Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, while the beam is activated or with any planned change of absorbed dose distribution. It includes, but is not limited to, arc, skip, conformal, and rotational therapy.

"Nominal treatment distance" means:

(1) 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.

(2) For x-ray irradiation, the distance from 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.

"Operator" means a person who, by virtue of training and experience is authorized by the registrant or authorized user, to operate a therapeutic radiation machine:

(1) for human use, and who meets the requirements of 24.3.5.1; or

(2) for veterinary use, and who meets the requirements of 24.3.5.2.

"Patient", for purposes of Part 24, means a human individual or animal to whom machine-produced radiation is delivered for medical therapy.

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

"Periodic quality assurance check" means a procedure performed periodically to ensure that a previous parameter, condition, or function continues to be valid.

"Personal supervision". See Part 1 definition.

"Prescribed dose" means the total dose and dose per fraction intended to a particular point or volume as documented in the written directive.

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

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

"Protective barrier" means a barrier of radiation-absorbing material(s) used to reduce radiation exposure. The types of protective barriers include:

(1) "Primary protective barrier", which means the material, excluding filters, placed in the useful beam;

(2) "Secondary protective barrier", which means the material that attenuates stray radiation.

"Registered medical physicist" (RMP) for radiation therapy means an individual who meets the applicable requirements of Part 2, Appendix 2B and has current Department approval to perform medical physics activities as a registered qualified expert for radiation therapy, including to design shielding, measure ionizing radiation, and oversee radiation protection and quality assurance at radiation therapy and other medical facilities.

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

"Radiation field". See "useful beam".

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

"Radiation therapist" means an individual who meets the requirements of Part 2, Appendix 2L.

"Radiation therapy" means the therapeutic application of ionizing radiation to humans or animals for medical, research, or veterinary purposes.

"Radiation therapy physician" means a physician trained to use therapeutic radiation machines on humans.

"Radiation therapy veterinarian" means a veterinarian trained to use therapeutic radiation machines on animals.

"Radiotherapy". See "radiation therapy".

"Redundant beam monitoring system" means a combination of two dose-monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

"Reportable medical event" means an event that meets the criteria in 24.6. For purposes of Part 24, "misadministration" is an equivalent term.

"Scattered primary radiation" means radiation that has been deviated in direction only by materials irradiated by the useful beam.

"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.

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

"Secondary protective barrier". See "protective barrier".

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

"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.

"Simulator" (radiation therapy simulation system) means:

(1) Any radiographic/fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing and reproducing the position and size of the therapeutic irradiation field; or

(2) A computed tomography system, which is used in conjunction with relevant software that recreates the treatment machine, and which allows import, manipulation, display and storage of images from computed tomography and/or other imaging modalities.

"Source-skin distance" (SSD). See "target-skin distance".

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Stereotactic body radiation therapy (SBRT)" means a specialized form of radiation therapy of the body (other than intracranial or spinal lesions) which uses a known three dimensional reference system to localize and deliver high doses of radiation to a target lesion with high precision in large fraction sizes over a short course (typically 5 or fewer fractions) of treatment.

"Stereotactic radiosurgery (SRS)" means a specialized form of radiation therapy of the brain and spine, and which uses a known three dimensional reference system to localize and deliver high doses of radiation to a target lesion with high precision in large fraction sizes over a short course of treatment.

"Stray radiation" means the sum of leakage radiation and scattered radiation.

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

"Target-skin distance" (TSD) means the distance measured along the beam axis from the center of the front surface of the x-ray target, or electron virtual source, or the nominal position of the electron source to the surface of the irradiated object or patient.

"Tenth-value layer" (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 of the value measured at the same point without the material.

"Termination of irradiation" means the stopping of irradiation in a manner that will not permit continuance of irradiation without the resetting the operating condition(s) at the control panel.

"Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for radiation therapy, including external beam and electronic brachytherapy systems.

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

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

"Useful beam" means the portion of ionizing radiation originating from the radiation head of the therapy system intended for therapeutic purposes. See "leakage radiation".

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

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

"Written directive" means an order in writing for the administration of radiation to a specific human patient or human research subject, in accord with the requirements of 24.6.

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

GENERAL REQUIREMENTS

24.3 General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

24.3.1 Administrative Controls.

24.3.1.1 Each therapeutic radiation machine shall be registered with the Department.

24.3.1.2 The registrant shall be responsible for directing operation of the therapeutic radiation machine, including designation of each authorized user and/or machine operator.

24.3.1.3 The registrant or the registrant's agent shall ensure that all applicable requirements of Part 24 are met in the operation of the therapeutic radiation machine.

24.3.1.4 A therapeutic radiation machine that does not meet the requirements of Sections 24.7, 24.8 or 24.13, as applicable, shall not be used to treat a patient without written authorization from the Registered Medical Physicist and Authorized User.

24.3.1.5 For a therapeutic radiation machine used only for veterinary applications, the registrant may request exemption from a requirement of Part 24 that is not applicable to the practices of veterinary medicine.

24.3.2 Supervision of Use.

24.3.2.1 Human use of a therapeutic radiation machine shall be by, or under the general supervision of, an authorized user radiation therapy physician who has a current active State of Colorado license to practice the healing arts.

24.3.2.2 The use of a therapeutic radiation machine for veterinary applications shall be by, or under the general supervision of, a radiation therapy veterinarian who has a current active State of Colorado license to practice veterinary medicine.

24.3.3 Training for an Authorized User of a Therapeutic Radiation Machine.

24.3.3.1 The registrant for a therapeutic radiation machine subject to 24.7, 24.8, 24.13 or 24.14 shall require each authorized user (radiation therapy physician) to meet the requirements of Part 2, Appendix 2K.

24.3.4 Training for a Radiation Therapy Registered Medical Physicist.

24.3.4.1 The registrant for a therapeutic radiation machine subject to 24.7, 24.8, 24.13, or 24.14 shall require each radiation therapy Registered Medical Physicist to be registered with the Department on the basis of training and experience in the clinical applications of radiation physics to radiation therapy.

24.3.5 Qualifications of a Therapeutic Radiation Machine Operator.

24.3.5.1 Each individual who will be operating a therapeutic radiation machine for human use shall be:

(1) An authorized user who meets the requirements of Part 2, Appendix 2K; or

(2) An individual, designated by a facility authorized user, who meets the requirements of Part 2, Appendix 2L, "Radiation Therapist Adequate Radiation Safety Training and Experience".

24.3.5.2 Each individual who will be operating a therapeutic radiation machine for veterinary use shall meet qualification criteria specified by a radiation therapy veterinarian supervising as provided in 24.3.2.2.

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

24.3.5.4 The name and training of each former operator shall be retained for a period of at least two (2) years beyond the last date the individual was authorized to operate a therapeutic radiation machine at that facility.

24.3.6 Written safety procedures and rules shall be developed by a Registered Medical Physicist.

24.3.6.1 These safety procedures and rules 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.

24.3.6.2 The operator shall be able to demonstrate familiarity with these safety procedures and rules.

24.3.7 Operating procedures required by 24.7.18 and 24.8.18 shall specify how the Registered Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Registered Medical Physicist can be contacted.

24.3.8 No individual shall be exposed to the useful beam except for medical therapy purposes pursuant to a written directive by an authorized user.

24.3.8.1 Deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes is strictly prohibited.

24.3.9 Each individual 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.

24.3.10 Record Maintenance and Retention.

24.3.10.1 The registrant shall maintain records, for inspection by the Department, in a separate file or location for each therapeutic radiation machine, including:

(1) Reports of acceptance testing;

(2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Part 24, as well as the name(s) of the 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 the person(s) who performed such services; and

(4) Each authorization, in accordance with a written procedure approved by the Registered Medical Physicist, for the return to use of a therapeutic radiation machine after service, repair, or upgrade.

24.3.10.2 All records required by Part 24 shall be retained for a period of at least three (3) years from the date of completion in accordance with Section 2.6.5 of Part 2.

24.4 General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

24.4.1 Protection Surveys.

24.4.1.1 The registrant shall ensure that a radiation protection survey of each facility, new or existing, has been performed with an operable radiation measurement survey instrument calibrated in accordance with 24.12.

(1) The radiation protection survey shall be performed by, or under the personal supervision of, a Registered Medical Physicist; and

(2) The radiation protection survey shall verify, with the therapeutic radiation machine in a "BEAM-ON" condition and the machine parameters set to produce the maximum scattering and leakage conditions, that:

(a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 4.6.1; and

(b) Radiation levels in unrestricted areas do not exceed the limits specified in 4.14.1.

24.4.1.2 In addition to the requirements of 24.4.1.1, a radiation protection survey shall also be performed:

(1) Prior to the first medical use of each therapeutic radiation machine;

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

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

(4) After relocating the therapeutic radiation machine; or

(5) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels, relative to the levels measured and documented in the last survey, in areas outside the radiation therapy treatment room.

24.4.1.3 The survey record shall indicate all instances where the radiation levels exceed the requirements of Sections 4.6.1 or 4.14.1, as applicable. The survey record shall include:

(1) The date of the measurement(s);

(2) The reason the survey is required;

(3) The name of the manufacturer of the therapeutic radiation machine;

(4) The model number and serial number of the therapeutic radiation machine;

(5) The instrument(s), with calibration details, used to measure radiation levels;

(6) A map of the areas surrounding the treatment room that were surveyed;

(7) The measured dose rate at several points in each area expressed in microsievert (or millirem) per hour;

(8) The calculated maximum radiation dose for each restricted and unrestricted area to demonstrate compliance with Sections 4.14.1.1., and 4.14.1.2. of Part 4; and

(9) The signature of the individual performing or exercising personal supervision of the survey.

24.4.1.4 If the result of a survey required by 24.4.1.1 or 24.4.1.2 indicates any radiation level in excess of the respective limit specified in 24.4.1.1, the registrant shall lock the control in the "OFF" position and shall not use the unit for treatment of patients.

(1) With prior approval of the Department, the therapeutic radiation machine may be used as necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding.

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

24.4.2.1 If the survey required by 24.4.1 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 4.14.1, 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 4.14.1;

(2) Perform the survey required by 24.4.1 again; and

(3) Include in the records required by 24.4.4 the results of the initial survey, a description of the modification made to comply with 24.4.2.1, and the results of the second survey; or

(4) Request and receive an authorization under 4.14.3 allowing radiation levels in unrestricted areas greater than those permitted by 4.14.1.

24.4.3 Dosimetry Equipment.

24.4.3.1 The registrant shall have a calibrated dosimetry system available for use.

(1) 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);

(2) The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration; and

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

24.4.3.2 The registrant shall have available for use a dosimetry system for quality assurance check measurements.

(1) To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 24.4.3.1.

(2) This comparison shall have been performed within the previous twelve (12) months and after each servicing that may have affected system calibration.

(3) The quality assurance check system may be the same system used to meet the requirement in 24.4.3.1.

24.4.3.3 The registrant shall maintain a record of each dosimetry system calibration or (inter)comparison for the duration of the license and/or registration, including for each calibration or (inter)comparison:

(1) The date;

(2) The model numbers and serial numbers of the instruments that were calibrated or (inter)compared as required by 24.4.3.1 and 24.4.3.2;

(3) The correction factors that were determined;

(4) The names of the individuals who performed the calibration or (inter)comparison; and

(5) Evidence that:

(a) Calibration was performed by the Accredited Dosimetry Calibration Laboratory (ADCL); or

(b) The intercomparison was performed by, or under the personal supervision of, a Registered Medical Physicist.

24.4.4 Records of Radiation Therapy Surveys and Measurements.

24.4.4.1 The registrant for any therapeutic radiation machine subject to 24.7 or 24.8 shall maintain a copy of the records required in 24.4.1 and 24.4.2 for Department inspection in accordance with 2.6.5.4.

24.4.5 Shielding and Safety Design Requirements.

24.4.5.1 Each therapeutic radiation machine subject to 24.7 or 24.8 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 4.6 and 4.14.

24.4.5.2 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 meet the minimum requirements of Appendix 24A and shall be submitted to a Department-approved qualified expert for radiation therapy for approval prior to actual installation of the therapeutic radiation machine.

24.5 Registered Medical Physicist Support.

24.5.1 In a facility having a therapeutic radiation machine, the Registered Medical Physicist shall perform the following:

24.5.1.1 Full calibration(s) required by 24.7.16 and 24.8.19;

24.5.1.2 Protection surveys required by 24.4.1;

24.5.1.3 Supervision and review of dosimetry;

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

24.5.1.5 Surveys of residual radioactivity required by 24.8.17;

24.5.1.6 General supervision of quality assurance, including establishing written procedures and reviewing quality assurance checks as required by 24.7.17 and 24.8.20.

24.5.1.7 Consultation with the authorized user in treatment planning, as needed; and

24.5.1.8 Calculations/assessments regarding a reportable medical event.

24.5.2 The Registered Medical Physicist shall be available for problems or emergencies consistent with the procedure specified pursuant to 24.3.7.

24.6 Quality Management Program.

24.6.1 Each registrant or applicant subject to 24.7, 24.8, 24.13, or 24.14 shall develop, implement, and maintain a quality management program to ensure that radiation will be administered as directed by the authorized user.

24.6.2 The quality management program shall include provisions for written directives and procedures for administration of radiation.

24.6.2.1 A written directive:

(1) Shall be dated and signed by a radiation therapy authorized user prior to the administration of radiation;

(2) Shall contain the human 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;

(3) May be revised at the discretion of the authorized user, provided that the revision is written, dated and signed by the authorized user prior to administration of the next fraction;

(4) May be subject to oral revision, if because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, and provided that:

(a) The oral revision is documented as soon as possible in writing in the patient's record; and

(b) A revised written directive is signed by an authorized user within 48 hours of the oral revision; and

(5) Shall be retained (a copy is acceptable) for 3 years.

24.6.2.2 The registrant shall develop, implement, and maintain written procedures to ensure that:

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

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

(3) Radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

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

(b) Verifying that any computer-generated calculations are correctly transferred into the consoles of therapeutic medical units;

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

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

24.6.3 Reports and Notifications of Reportable Medical Events.

24.6.3.1 A registrant shall report any event resulting from intervention of a human patient or human research subject in which the administration of any beam radiotherapy results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

24.6.3.2 Other than events that result from intervention by a human patient or human research subject, a registrant shall report any event in which the delivered dose to the prescribed point or volume:

(1) Involved the wrong individual or the wrong treatment site; or

(2) Involved:

(a) A calculated administered dose that differs from the:

(i) Total prescribed dose by more than 10 percent of the total prescribed dose, for a total prescribed dose consisting of three (3) or fewer fractions; or

(ii) Total prescribed dose by more than 20 percent of the total prescribed dose; or

(iii) Weekly prescribed dose by more than 30 percent.

24.6.3.3 The registrant shall notify the Department by telephone no later than the next calendar day after discovery of the reportable medical event.

24.6.3.4 The registrant shall submit a written report to the Department within 15 calendar days after discovery of the reportable medical event pursuant to 24.6, to include:

(1) The registrant or licensee's name;

(2) The name of the authorized user who signed the written directive and/or who supervised delivery of the prescribed dose;

(3) The name(s) of the Registered Medical Physicist(s);

(4) The name(s) of the radiation therapist(s);

(5) A brief description of the event;

(6) Why the event occurred;

(7) The room the event occurred in;

(8) The type of radiotherapy equipment involved in the event;

(9) Copies of written protocols;

(10) The effect, if any, on the individual who received the dose;

(11) Actions, if any, that have been taken, or are planned, to prevent recurrence; and

(12) Certification that the registrant notified the individual who received the dose (or the individual's responsible relative or guardian) or, if not, the reason notification was not provided.

24.6.3.5 The report shall not contain the affected individual's name or any other information that could lead to identification of the individual who received the dose.

24.6.3.6 The registrant shall provide notification of the reportable medical event, no later than 24 hours after its discovery, to the authorized user (and to the referring physician if other than the authorized user).

24.6.3.7 The registrant shall notify the affected individual no later than 24 hours after the reportable medical event is discovered, unless, based on medical judgment, the authorized user informs the registrant in writing that telling the individual would be harmful.

(1) The registrant shall notify the affected individual as soon as possible if the authorized user cannot be reached within 24 hours.

(2) The registrant shall not delay any appropriate medical care for the affected individual, including any necessary remedial care as a result of the reportable medical event, because of any delay in notification.

(3) To meet the requirements of this section, the notification of the affected individual may be made instead to that individual's responsible relative or guardian.

(4) If a verbal notification is made, the registrant shall inform the affected individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

24.6.3.8 Aside from the notification requirement, nothing in this section affects any rights or duties of registrants, licensees, and physicians in relation to each other, to an individual affected by the reportable medical event, or to that individual's responsible relatives or guardians.

24.6.3.9 A registrant shall retain a record of a reportable medical event for 3 years, containing:

(1) The registrant’s or licensee's name;

(2) The name of each individual involved;

(3) The medical records number or equivalent means to identify the individual who is the subject of the reportable medical event;

(4) A brief description of the event and why it occurred;

(5) The effect, if any, on any individual who received the dose;

(6) The actions, if any, taken, or planned, to prevent recurrence; and

(7) Whether the registrant notified the individual (or the individual's responsible relative or guardian) or, if not, the reason notification was not provided.

24.6.3.10 A copy of the record required under 24.6.3.9 shall be provided to the authorized user(s), if other than the registrant or licensee, within 15 calendar days after discovery of the reportable medical event.

SPECIFIC REQUIREMENTS

24.7 Therapeutic Radiation Machines of Less Than 500 kV.

24.7.1 Leakage Radiation.

24.7.1.1 For each therapeutic radiation machine, the registrant shall determine for all systems the maximum leakage radiation at 5 centimeters from the tube housing assembly, and also at 1 meter from the target for systems > 50 to < 500 kV, or obtain equivalent measured and published data from the manufacturer or by other means acceptable to the Department.

24.7.1.2 When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate:

(1) For systems 5 to 50 kV, shall not exceed 1 mGy (100 mrad) in any one hour, measured at any position 5 centimeters from the tube housing assembly.

(2) For systems > 50 to < 500 kV, shall not exceed 1 cGy (1 rad) in any one hour, measured at a distance of 1 meter from the target in any direction.

(a) This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters.

(b) In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

24.7.1.3 Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

24.7.2 Permanent Beam Limiting Devices.

24.7.2.1 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.

24.7.3 Adjustable or Removable Beam Limiting Devices.

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

24.7.3.2 When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam, as applicable to the device as originally manufactured.

24.7.4 Filter System.

24.7.4.1 The filter system shall be so designed that:

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

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

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

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

24.7.5 Tube Immobilization.

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

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

24.7.6 Source Marking.

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

24.7.7 Beam Block.

24.7.7.1 On contact therapy systems, a shield of at least 0.5 millimeters of lead equivalency at 100 kV shall be positioned over the entire useful beam exit port during periods when the tube is energized and the beam is not in use.

24.7.8 Timer.

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

24.7.8.2 The timer required by 24.7.8.1 shall:

(1) Have a display at the treatment control panel;

(2) Have a pre-set time selector and an elapsed time or time remaining indicator;

(3) Be a cumulative timer 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;

(4) Terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(5) Permit accurate pre-setting and determination of exposure times as short as one second;

(6) Not permit an exposure if set at zero;

(7) 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

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

24.7.9 Control Panel Functions.

24.7.9.1 The control panel, in addition to the displays required by other provisions in 24.7, 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) A means for indicating x-ray tube potential and current;

(4) A 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 September 30, 1999, a positive display of specific filter(s) in the beam.

24.7.10 Multiple Tubes.

24.7.10.1 When a control panel may energize more than one x-ray tube:

(1) Only one x-ray tube shall activate at any time;

(2) The control panel shall have an indicator that identifies which x-ray tube is activated; and

(3) An indicator at the tube housing assembly shall identify when that tube is energized.

24.7.11 Target-Skin Distance (TSD).

24.7.11.1 Means shall be provided to determine the central axis TSD to within one centimeter and to reproduce this measurement to within 2 millimeters thereafter.

24.7.12 Shutters.

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

(1) In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel.

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

24.7.13 Low Filtration X-ray Tubes.

24.7.13.1 Each therapeutic radiation machine equipped with a beryllium or other low-filtration window (HVL < 0.1 mm of Al) 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.

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

24.7.14.1 In addition to shielding adequate to meet requirements of 24.4.5, the treatment room shall meet the following design requirements:

(1) Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel, except for an intraoperative radiotherapy (IORT) room where the patient is under general anesthesia and no staff remain in the room.

(2) Viewing Systems.

(a) Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation.

(b) The viewing system shall be so located that the operator may observe the patient from the treatment control panel.

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

24.7.15 Additional Requirements.

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

(1) All protective barriers shall be fixed except for entrance doors or beam interceptors;

(2) The control panel shall be located outside the treatment room or in a totally enclosed booth;

(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 24.7.15.1(3) is opened while the x-ray tube is activated, the air kerma rate in the useful beam at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

24.7.16 Full Calibration Measurements.

24.7.16.1 Full calibration of a therapeutic radiation machine subject to 24.7 shall be performed by, or under the personal supervision of, a Registered Medical Physicist:

(1) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(2) At intervals not exceeding one year; 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 (5) percent 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 24.7.16.1(3):

(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 use in treatments at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 24.7.16.1(3)(a).

24.7.16.2 To satisfy the requirement of 24.7.16.1, full calibration shall include all measurements recommended for annual calibration by AAPM Report 46, or AAPM Task Group 142 report unless the Registered Medical Physicist determines that a particular recommendation of these reports is not warranted for the clinical tasks for which the equipment will be used, or is not applicable to the type of therapy device in use. Deviations from these guidance documents shall be documented in the written procedures.

24.7.16.3 The registrant shall maintain a record of each calibration for the duration of the registration, to include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;

(3) The manufacturer's name, model number and serial number for the instrument(s) used to calibrate the therapeutic radiation machine; and

(4) The signature of the Registered Medical Physicist performing or exercising personal supervision of the calibration.

24.7.17 Periodic Quality Assurance Checks.

24.7.17.1 Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to 24.7, which are capable of operation at greater than or equal to 50 kV.

24.7.17.2 To satisfy the requirement of 24.7.17.1, quality assurance checks shall meet the following requirements:

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

(2) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed.

(a) The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 24.7.16.1.

(b) 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 24.7.16.1, shall be stated.

24.7.17.3 The cause for a parameter exceeding a tolerance set by the Registered Medical Physicist shall be investigated and corrected before the system is used for patient irradiation.

24.7.17.4 Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Registered Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in 24.7.16.1.

24.7.17.5 The registrant shall use the dosimetry system described in 24.4.3 to make the quality assurance check required in 24.7.17.2.

24.7.17.6 The registrant shall have the Registered Medical Physicist review and sign the results of each radiation output quality assurance check within one month of the date that the check was performed.

24.7.17.7 The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 24.7 are performed at intervals not to exceed one month.

24.7.17.8 Notwithstanding the requirements of 24.7.17.6 and 24.7.17.7, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 24.7.17.6 and 24.7.17.7 have been performed within the 30 day period immediately prior to said administration.

24.7.17.9 To satisfy the requirement of 24.7.17.7, safety quality assurance checks shall ensure proper operation of:

(1) Electrical interlocks at each radiation therapy room entrance;

(2) The "BEAM-ON" and termination switches;

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

(4) Viewing systems; and

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

24.7.17.10 The registrant shall maintain a record of each quality assurance check required by 24.7.17.1 and 24.7.17.7 for three (3) years, including:

(1) The date of the quality assurance check;

(2) The manufacturer's name, model number, and serial number of the therapeutic radiation machine;

(3) The manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and

(4) The signature of the individual who performed the periodic quality assurance check.

24.7.18 Operating Procedures.

24.7.18.1 The therapeutic radiation machine shall not be used for irradiation of a patient unless the requirements of 24.7.16 and 24.7.17 have been met;

24.7.18.2 Therapeutic radiation machines shall not be left unattended unless secured pursuant to 24.7.9.1(5);

24.7.18.3 When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

24.7.18.4 The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV.

(1) In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

24.7.18.5 A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

24.7.18.6 No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV.

24.7.18.7 At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 4.6.

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

24.8.1 Facility Design Requirements in Addition to Shielding Required by 24.4.5 and Appendix 24A.

24.8.1.1 All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

24.8.1.2 The control panel, in addition to other requirements specified in Part 24, shall:

(1) Be located outside the treatment room;

(2) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(3) Provide an indication of whether radiation is being produced; and

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

24.8.1.3 Viewing Systems.

(1) Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation.

(2) The viewing system shall be so located that the operator may observe the patient from the treatment control panel.

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

24.8.1.4 Communication.

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

(2) The therapeutic radiation machine shall not be used for irradiation of a patient unless continuous two-way communication is possible.

24.8.1.5 Room Entrances.

(1) Each treatment room entrance shall be provided with a warning light, in a readily observable position near the outside of each access door or entrance, that will indicate when the useful beam is "ON" and when it is "OFF".

24.8.1.6 Entrance Interlocks.

(1) Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continue.

(2) 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.

24.8.1.7 Beam Interceptor Interlocks.

(1) If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 4.14.1, 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 barriers.

24.8.1.8 Emergency Cutoff Switches.

(1) At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 24.8.11.

(2) 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.

24.8.1.9 Safety Interlocks.

(1) 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.

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

24.8.2.1 The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

24.8.2.2 Except for the area defined in 24.8.2.1, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

24.8.2.3 For equipment manufactured after September 30, 1999, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission, Document 601-2-1, June 1998; and

24.8.2.4 For each therapeutic radiation machine, the registrant shall determine the leakage radiation existing at the positions specified in 24.8.2.1, 24.8.2.2 and 24.8.2.3 for the specified operating conditions, or obtain equivalent measured and published leakage radiation data from the manufacturer or by other means acceptable to the Department.

24.8.2.5 Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

24.8.3 Leakage Radiation Through Beam Limiting Devices.

24.8.3.1 Photon Radiation.

(1) All adjustable or interchangeable beam limiting devices, excluding secondary custom blocks, 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 (2) percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeter by 10 centimeter radiation field;

24.8.3.2 Electron Radiation.

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

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

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

24.8.3.3 Measurement of Leakage Radiation.

(1) Photon Radiation.

(a) 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 (TVL) 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.

(b) Measurements shall be made using a radiation detector of area not exceeding 10 square centimeters;

(2) Electron Radiation.

(a) 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 suitably protected against radiation that has been scattered from material beyond the radiation detector.

(b) Measurements shall be made using one centimeter of water equivalent build-up material.

24.8.4 Filters/Wedges.

24.8.4.1 Each wedge filter that is removable from the system shall be clearly marked with an identification number.

24.8.4.2 For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray).

24.8.4.3 If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be re-determined;

24.8.4.4 For equipment manufactured after September 30, 1999, which utilizes wedge filters, interchangeable 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 as selected by the operator or as required by the energy/mode selected by the operator;

(3) A display shall be provided at the treatment control panel showing the wedge filter(s); and

(4) An interlock shall be provided to prevent irradiation if there is a mismatch between the filter and/or beam scattering foil selected by the operator or required for the energy/modality selected by the operator.

24.8.4.5 If the absorbed dose rate information required by 24.8.9 relates exclusively to operation with a field-flattening filter or beam scattering foil in place, such foil or filter shall be removable from the therapeutic radiation machine only by the use of tools;

24.8.5 Stray Radiation in the Useful Beam.

24.8.5.1 The registrant shall determine during acceptance testing, or obtain from the manufacturer or by other means acceptable to the Department, measured and published 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, Document 601-2-1, June 1998, or equivalent criteria.

24.8.6 Beam Monitors.

24.8.6.1 All therapeutic radiation machines subject to 24.8 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

24.8.6.2 All therapeutic radiation machines subject to 24.8 shall be provided with at least two (2) independently powered integrating dose meters.

(1) Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

(2) Equipment manufactured on or before September 30, 1999, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system.

24.8.6.3 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) 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 systems; 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 September 30, 1999, each display shall:

(a) Maintain a reading until intentionally reset;

(b) Have only one 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 24.8.6.3(5)(c) 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.

24.8.7 Beam Symmetry.

24.8.7.1 Bent-beam linear accelerators subject to 24.8 shall be provided with auxiliary device(s) to monitor beam symmetry;

24.8.7.2 The device(s) required in 24.8.7.1 shall be able to detect field asymmetry greater than ten (10) percent; and

24.8.7.3 The device(s) required in 24.8.7.1 shall be configured to terminate irradiation if the specifications in 24.8.7.2 cannot be maintained.

24.8.8 Selection and Display of Dose Monitor Units.

24.8.8.1 Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

24.8.8.2 The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

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

24.8.8.4 For equipment manufactured after September 30, 1999, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

24.8.9 Air Kerma Rate/Absorbed Dose Rate.

24.8.9.1 For equipment manufactured after September 30, 1999, 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 24.8.6 may form part of this system.

24.8.9.2 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;

(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 4 Gy (400 rad); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer or by other means acceptable to the Department, the maximum value(s) specified in 24.8.9.2(2) and 24.8.9.3(3) for the specified operating conditions.

24.8.9.3 The following records shall be maintained at the installation for inspection by the Department:

(1) The dose rate at which the irradiation will be terminated pursuant to 24.8.9.2(2); and

(2) The maximum value(s) specified in 24.8.9.2(2) and 24.8.9.2(3).

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

24.8.10.1 Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

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

24.8.10.3 For equipment manufactured after September 30, 1999, an indicator on the control panel shall show which monitoring system has terminated irradiation.

24.8.11 Termination of Irradiation.

24.8.11.1 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.

24.8.12 Interruption of Irradiation.

24.8.12.1 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.

24.8.12.2 Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions.

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

24.8.13 Timer.

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

24.8.13.2 The timer shall:

(1) Have a display at the treatment control panel;

(2) Have a pre-set time selector and an elapsed time indicator;

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

(4) Require that the elapsed time indicator be reset after irradiation is terminated and before irradiation can be reinitiated; and

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

24.8.14 Selection of Radiation Type.

24.8.14.1 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 that 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.

24.8.15 Selection of Energy.

24.8.15.1 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 September 30, 1999, the selection of energy shall be in compliance with the current revision of International Electrotechnical Commission, Document 601-2-1 in effect at the time of equipment manufacture.

24.8.16 Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy.

24.8.16.1 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 that 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 September 30, 1999:

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

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

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

(iv) An interlock shall be provided to require that a selection, verification, or display of direction of rotation be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy;

(v) 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;

(iv) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 24.8.10; and

(b) For equipment manufactured after September 30, 1999, an interlock system shall be provided to terminate irradiation if movement:

(i) Occurs during stationary beam radiation therapy; or

(ii) Does not start or stop during moving beam radiation therapy unless such motion or stoppage is a pre-planned function.

24.8.17 Surveys for Residual Radiation.

24.8.17.1 Prior to machining, removing or working on a therapeutic radiation machine capable of generating photon and electron energies above 10 MV, a survey for residual activity of components that might have become activated due to photo-neutron production shall be conducted if the Registered Medical Physicist determines, consistent with 4.18.1.1, that 10% of the limits in 4.6 might be exceeded.

24.8.18 Operating Procedures.

24.8.18.1 No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

24.8.18.2 Therapeutic radiation machines shall not be made available for medical use unless the requirements of 24.4.1, 24.8.19 and 24.8.20 have been met;

24.8.18.3 Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

24.8.18.4 When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field, when available;

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

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

24.8.19 Acceptance Testing, Commissioning and Full Calibration Measurements.

24.8.19.1 Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 24.8 shall be performed by, or under the personal supervision of, a Registered Medical Physicist.

24.8.19.2 Acceptance testing and commissioning shall be:

(1) Performed in accordance with AAPM Report 47, unless the Registered Medical Physicist determines and documents that a particular recommendation of AAPM Report 47 is not warranted for the clinical tasks for which the equipment will be used;

(2) Performed in accordance with manufacturer's specifications, unless the Registered Medical Physicist determines and documents that a particular manufacturer recommendation is not warranted for the clinical tasks for which the equipment will be used; and

(3) Conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

24.8.19.3 Full calibration shall include measurement of all parameters required by Table II of AAPM Report 46 and shall be performed in accordance with AAPM Report 47, or AAPM Task Group 142 report, unless the Registered Medical Physicist determines and documents that a particular recommendation of these reports is not warranted for the clinical tasks for which the equipment will be used, or is not applicable to the type of therapy device in use.

(1) Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding twelve (12) calendar months, unless a more frequent interval is required in Table II of AAPM Report 46 or the AAPM Task Group 142 report.

24.8.19.4 All elements of a full calibration necessary to determine that all parameters are within acceptable limits shall be performed by, or under the personal supervision of, a Registered Medical Physicist:

(1) Whenever quality assurance check measurements indicate that the radiation output differs by more than five (5) percent from the value obtained at the last full calibration and the difference cannot be reconciled.

(a) 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.

(a) If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent use in treatments at the facility.

(b) The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 24.8.19.4(1).

24.8.19.5 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 therapeutic radiation machine;

(3) The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and

(4) The signature of the Registered Medical Physicist performing or exercising personal supervision of the calibration.

24.8.20 Periodic Quality Assurance Checks.

24.8.20.1 Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 24.8 at intervals not to exceed those specified in AAPM Report 46, or AAPM Task Group 142 report, unless the Registered Medical Physicist determines and documents that a particular recommendation of these reports is not warranted for the clinical tasks for which the equipment will be used, or is not applicable to the type of therapy device in use;

24.8.20.2 To satisfy the requirement of 24.8.20.1, quality assurance checks shall include determination of central axis radiation output and periodic quality assurance checks contained in AAPM Report 46, or AAPM Task Group 142 report unless the Registered Medical Physicist determines and documents that a particular recommendation of these reports is not warranted for the clinical tasks for which the equipment will be used, or is not applicable to the type of therapy device in use;

24.8.20.3 The registrant shall use the dosimetry system described in 24.4.3.1, or a dosimetry system that has been inter-compared within the previous twelve (12) months with the dosimetry system consistent with 24.4.3.2, to make the periodic quality assurance checks required in 24.8.20.2;

24.8.20.4 The registrant shall perform periodic quality assurance checks required by 24.8.20.1 in accordance with procedures and frequencies established by the Registered Medical Physicist;

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

(1) An authorized user or a Registered Medical Physicist shall be immediately notified if any radiation output parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until a Registered Medical Physicist has determined that all radiation output parameters are within their acceptable tolerances; and

(2) If all radiation output check parameters appear to be within their acceptable range, the radiation output check shall be reviewed and signed by either an authorized user or a Registered Medical Physicist weekly;

24.8.20.6 Safety quality assurance checks listed in AAPM Report 46 or AAPM Task Group 142 report shall be performed for therapeutic radiation machines subject to 24.8, unless the Registered Medical Physicist determines, and documents in writing, that a particular recommendation of these reports is not warranted for the clinical tasks for which the equipment will be used, or are not applicable to the type of therapy device in use;

24.8.20.7 As a minimum, the following safety quality assurance checks, as applicable to the machine, shall be performed by or under the general supervision of the Registered Medical Physicist, and at intervals not to exceed one week, unless otherwise specified below:

(1) Electrical interlocks at each radiation therapy room entrance;

(2) Proper operation of the "BEAM-ON", interrupt and termination switches;

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

(4) Viewing systems;

(5) Electrically operated treatment room door(s) from inside and outside the treatment room; and

(6) Each month, at least one emergency power cutoff switch shall be tested, except where a lesser frequency is otherwise specified in writing by the manufacturer.

(a) If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis.

(b) Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

24.8.20.8 The registrant shall promptly repair any system identified in 24.8.20.7 that is not operating properly; and

24.8.20.9 The registrant shall maintain a record of each quality assurance check required by 24.8.20.1 and 24.8.20.7 for three (3) years. The record shall include:

(1) The date of the quality assurance check;

(2) The manufacturer's name, model number, and serial number of the therapeutic radiation machine;

(3) The manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and

(4) The signature of the individual who performed the periodic quality assurance check.

24.8.21 Quality Assurance Checks for Intensity Modulated Radiation Therapy (IMRT) shall:

24.8.21.1 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;

24.8.21.2 Be performed in accordance with AAPM Report 82, unless the Registered Medical Physicist determines and documents that a particular recommendation of AAPM Report 82 is not warranted for the clinical tasks for which the equipment will be used; and

24.8.21.3 Be performed in accordance with the manufacturer’s specifications.

24.9 Quality Assurance For Radiation Therapy Simulation Systems.

24.9.1 Quality assurance for a simulator shall include acceptance testing and periodic verification of system performance; and

24.9.2 Be performed (unless the Registered Medical Physicist determines and documents that a particular recommendation is not warranted for the clinical task for which the equipment will be used) in accordance with:

24.9.2.1 AAPM Report 46, for a radiographic/fluoroscopic simulator; or

24.9.2.2 AAPM Report 83 for a computed tomography based simulator.

24.10 Quality Assurance for Image Guided Radiation Therapy

24.10.1 Quality assurance for a radiographic/fluoroscopic IGRT system shall be performed by or under the direct supervision of a Registered Medical Physicist, and shall include acceptance testing and periodic verification of system performance in accordance with manufacturer’s specifications and the AAPM Task Group 179 report unless the Registered Medical Physicist determines, and documents in writing, that a particular recommendation of these reports is not warranted for the clinical tasks for which the equipment will be used.

24.11 Possession of Survey Instrument(s).

24.11.1 Each facility location authorized to use a therapeutic radiation machine in accordance with 24.7 or 24.8 shall possess appropriately calibrated portable radiation monitoring equipment, including:

24.11.1.1 At least one portable radiation measurement survey instrument that is:

(1) Capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour;

(2) Operable; and

(3) Calibrated in accordance with 24.12.

24.12 Calibration of Survey Instruments.

24.12.1 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 twenty-four (24) months, and following repair.

24.12.2 To satisfy the requirements of 24.12.1, the registrant shall:

24.12.2.1 Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST); and

24.12.2.2 Calibrate at least two (2) points, at approximately 1/3 and 2/3 of full-scale, on each scale to be calibrated; and

24.12.3 To satisfy the requirements of 24.12.2, the registrant shall:

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

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

24.12.4 The registrant may obtain the services of individuals licensed by the Department, NRC, an Agreement State, or a Licensing State to perform calibrations of survey instruments.

24.12.5 The registrant shall retain a record of each calibration required in 24.12.1 for three (3) years. The record shall include:

24.12.5.1 A description of the calibration procedure;

24.12.5.2 A description of the source used;

24.12.5.3 The certified dose rates from the source;

24.12.5.4 The rates indicated by the instrument being calibrated;

24.12.5.5 The correction factors deduced from the calibration data;

24.12.5.6 The signature of the individual who performed the calibration; and

24.12.5.7 The date of calibration.

24.13 Electronic Brachytherapy.

24.13.1 Electronic brachytherapy devices shall be subject to the requirements of 24.13, and shall be exempt for the requirements of 24.7.

24.13.1.1 An electronic brachytherapy device that does not meet the requirements of 24.13 shall not be used for irradiation of patients; and

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

24.13.2 Each facility location authorized to use an electronic brachytherapy device in accordance with 24.13 shall possess portable radiation monitoring equipment in accord with 24.11 that is operable and calibrated in accordance with 24.12 for the applicable electronic brachytherapy source energy.

24.13.3 In addition to shielding adequate to meet requirements of 24.4.5, the treatment room shall meet the following design requirements:

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

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

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

24.13.3.4 For electronic brachytherapy devices capable of operating below 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.

24.13.3.5 For electronic brachytherapy devices capable of operating at greater than 150 kV:

(1) The control panel shall be located outside the treatment room; and

(2) Electrical interlocks shall be provided for all door(s) to the treatment room that will:

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

(b) Cause the source to be shielded when an entrance door is opened; and

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

24.13.4 Electrical Safety for Electronic Brachytherapy Devices.

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

24.13.4.2 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.

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

24.13.4.4 Equipment manufactured after 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.

24.13.5 The control panel, in addition to the displays required by other provisions in 24.13, shall:

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

24.13.5.2 Provide an indication of whether x rays are being produced;

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

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

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

24.13.6 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.

24.13.6.1 A timer shall be provided at the treatment control panel and shall indicate planned setting and the time elapsed or remaining;

24.13.6.2 The timer shall not permit an exposure if set at zero;

24.13.6.3 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;

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

24.13.6.5 The timer shall permit setting of exposure times as short as 0.1 second; and

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

24.13.7 Registered Medical Physicist Support.

24.13.7.1 In each facility having an electronic brachytherapy device, a Registered 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 24.13.11;

(5) Consultation with the authorized user in treatment planning, as needed; and

(6) Performing calculations/assessments regarding patient treatments that may constitute a reportable medical event as provided in 24.6.3.

24.13.7.2 The operating procedures required by 24.13.8 shall specify how the Registered Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Registered Medical Physicist is contacted.

24.13.8 Operating Procedures.

24.13.8.1 Only individuals approved by the authorized user, Radiation Safety Officer, or Registered Medical Physicist shall be present in the treatment room during treatment;

24.13.8.2 Electronic brachytherapy devices shall not be made available for medical use unless the requirements of 24.4.1, 24.13.9 and 24.13.10 have been met;

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

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

(1) The electronic brachytherapy device shall not be used for human patient irradiation unless the patient can be observed as provided in 24.13.3.3.

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

24.13.8.6 Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation, including:

(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 Registered Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

24.13.8.7 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 device operation;

24.13.8.8 Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Registered Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally;

(1) If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during device operation; and

24.13.8.9 If the patient has a medical emergency, suffers injury or dies, the Radiation Safety Officer, or RSO's designee, and an authorized user shall be notified as soon as possible but no later than 48 hours after the event.

24.13.9 Safety Precautions for Electronic Brachytherapy Devices.

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

24.13.9.2 An authorized user and a Registered Medical Physicist shall be physically present during the initiation of all human patient treatments involving the electronic brachytherapy device;

24.13.9.3 A Registered Medical Physicist and either an authorized user or a physician or electronic brachytherapy device operator, under the personal 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 human patient treatments involving the electronic brachytherapy device;

24.13.9.4 When shielding is required by 24.13.3.4, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Registered Medical Physicist shall designate shield locations sufficient to meet the requirements of Part 4 of these regulations for any individual, other than the patient, in the treatment room; and

24.13.9.5 All personnel in the treatment room are required to remain behind shielding during treatment. A Registered 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.

24.13.10 Electronic Brachytherapy Source Calibration Measurements.

24.13.10.1 Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to 24.13 shall be performed by, or under the direct supervision of, a Registered Medical Physicist;

24.13.10.2 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;

24.13.10.3 Calibration of the electronic brachytherapy source output shall utilize a dosimetry system described in 24.4.3.

24.13.10.4 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;

24.13.10.5 Calibration of the x-ray source output required by 24.13.10.1 through 24.13.10.4 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.

24.13.10.6 The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration, including the:

(1) Date of the calibration;

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

(3) Unique identifier for the corresponding electronic brachytherapy source;

(4) Model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and

(5) Name and signature of the Registered Medical Physicist responsible for performing the calibration.

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

24.13.11.1 Quality assurance checks shall be performed on each electronic brachytherapy device subject to 24.13:

(1) At the beginning of each day of use;

(2) Each time the device is moved to a new room or site; and

(3) After each x-ray tube installation.

24.13.11.2 The registrant shall perform periodic quality assurance checks required by 24.13.11.1 in accordance with procedures established by the Registered Medical Physicist;

24.13.11.3 To satisfy the requirements of 24.13.11.1, radiation output quality assurance checks shall include as 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 24.13.10.; and

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

24.13.11.4 The registrant shall use a dosimetry system that meets the requirements of 24.4.3 to make the quality assurance checks required in 24.13.11.3.

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

(1) An authorized user and Registered 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 Registered 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 Registered Medical Physicist within two (2) days; and

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

24.13.11.6 To satisfy the requirements of 24.13.11.1 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.

24.13.11.7 If the results of the safety device quality assurance checks required in 24.13.11.6 indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

24.13.11.8 The registrant shall maintain a record of each quality assurance check required by 24.13.11.3 and 24.13.11.7 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 Registered Medical Physicist who reviewed the quality assurance check;

(2) For radiation output quality assurance checks required by 24.13.11.3, 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.

24.13.12 Acceptance Testing For Electronic Brachytherapy.

24.13.12.1 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).

(1) In the absence of an acceptance testing protocol published by a national professional association, the manufacturer’s acceptance testing protocol shall be followed.

24.13.12.2 Acceptance testing shall be performed by, or under the direct supervision of, a Registered Medical Physicist and shall include at a minimum, 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) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system, if the treatment-planning system is different from the treatment-delivery system.

24.13.12.3 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.

24.13.12.4 Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the authorized user and the Registered Medical Physicist for correctness through means independent of that used for the determination of the parameters.

24.13.13 Mobile Electronic Brachytherapy.

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

(1) Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.

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

(3) Perform, at each location on each day of use, all of the required quality assurance checks specified in 24.13.11 to assure proper operation of the device.

24.13.14 Training.

24.13.14.1 A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in 24.13.8. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

24.13.14.2. In addition to the requirements of 24.3.3 for therapeutic radiation machine authorized users and 24.3.4 for Registered Medical Physicists, these individuals shall also receive device-specific instruction initially from the manufacturer, and annually 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.

24.13.14.3. A registrant shall retain a record of individuals receiving instruction required by 24.13.14 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.

24.14 Stereotactic Radiosurgery/Stereotactic Body Radiotherapy

24.14.1. In addition to the requirements in Section 24.3, 24.4, 24.5, 24.6 and 24.8, registrants performing stereotactic radiosurgery or stereotactic body radiotherapy, shall follow the safety and quality assurance guidelines set forth in AAPM Task Group 101 Report and, the American Society for Radiation Oncology (ASTRO) report on "Quality and Safety Considerations in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy" (August, 2011) unless the Registered Medical Physicist determines that a particular recommendation of these reports is not warranted.

24.14.1.1 Deviations from the recommended acceptance, commissioning, or quality assurance criteria must be documented by the Registered Medical Physicist.

24.14.2 Supervision of SRS/SBRT Procedures

24.14.2.1 SRS/SBRT procedures shall be directly supervised by the Authorized User and the Registered Medical Physicist.

24.14.2.2 The initiation of the first fraction delivered in an SRS/SBRT procedure shall be personally supervised by the Authorized User or the Registered Medical Physicist.

24.15 Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage.

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

24.15.1.1. The applicant or registrant has, at a minimum, provided the Department with:

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

(2) Facility design requirements, including shielding and access control;

(3) Documentation of appropriate training for authorized user physician(s) and registered medical physicist(s)

(4) Methodology for measurement of dosages to be administered to patients or human research subjects;

(5) Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety

(6) Radiation safety precautions and instructions; and

(7) Other information requested by the Department in its review of the application; and

24.15.1.2 The applicant or registrant has received written approval from the Department to utilize the device in accordance with the regulations and specific conditions the Department considers necessary for the medical use of the device.

PART 24, APPENDIX 24A:

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

24A.1 All Therapeutic Radiation Machines.

24A.1.1 Basic facility information including: name, telephone number and facility registration number; registration number of the individual preparing the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

24A.1.2 All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

24A.1.3 Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

24A.2 Therapeutic Radiation Machines Up To 150 kV (photons only).

In addition to the requirements listed in 24A.1 above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall develop, document, and maintain on file, shielding plans which contain, as a minimum, the following additional information:

24A.2.1 Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

24A.2.2 Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter, total beam-on time or monitor units (MU) per day or week, the average treatment time or monitor units (MU) per patient, along with the anticipated number of patients to be treated per day or week;

24A.2.3 A facility drawing to scale indicating: the direction of North; normal location of the therapeutic radiation machine's radiation port(s); each port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. 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 4.6;

24A.2.4 The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

24A.2.5 The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present; and

24A.2.6 At least one 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, entry doors) and shielding material in the facility:

(1) If commercial software is used to generate shielding requirements, the software used and the version/ revision date shall be identified; or

(2) If the software used to generate shielding requirements is not in the open literature or commercially available, quality control sample calculations to verify the result obtained with the software shall be identified.

24A.3 Therapeutic Radiation Machines Over 150 kV.

In addition to the requirements listed in 24A.1 above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV and/or electrons shall develop, document, and maintain on file, shielding plans which contain, as a minimum, the following additional information:

24A.3.1 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 (photon, electron). The target to isocenter distance shall be specified;

24A.3.2 Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one 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;

24A.3.3 Facility drawing to scale [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, type(s), thickness and minimum density of shielding material(s), direction of North, 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;

24A.3.4 The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

24A.3.5 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;

24A.3.6 A description of all assumptions that were in shielding calculations including, but not limited to, design energy [i.e. a room may be designed for a 6 MV unit although only a 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 the useful beam will intercept each permanent barrier [walls, floor and ceiling] and the radiation exposure in both restricted and unrestricted areas; and

24A.3.7 At least one 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:

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/ revision date; or

(2) If the software used to generate shielding requirements is not in the open literature or commercially available, submit quality control sample calculations to verify the result obtained with the software.

24A.4 Neutron Shielding

In addition to the requirements listed in 24A.3 above, therapeutic radiation machine facilities that are capable of operating above 10 MV shall document, develop, and maintain on file, shielding plans which contain, as a minimum, the following additional information:

24A.4.1 The structural composition, thickness, minimum density and location of all neutron shielding material;

24A.4.2 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;

24A.4.3 At least one 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:

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; or

(2) If the software used to generate shielding requirements is not in the open literature or commercially available, submit quality control sample calculations to verify the result obtained with the software; and

24A.4.4 The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

Editor's Notes

6 CCR 1007-1 has been divided into separate parts for ease of use. Versions prior to 04/01/2007 are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the All Versions list on the rule's current version page. To view versions effective on or after 04/01/2007, select the desired part of the rule, for example 6 CCR 1007-1 Part 01 or 6 CCR 1007-1 Part 10.

History

Part 24 entire rule eff. 07/01/2010.

Part 24, Appendix 24A eff. 01/14/2014.