Title 15 - Mississippi Department of Health

Part III – Office of Health Protection

Subpart 78 – Division of Radiological Health

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CHAPTER 01 REGULATIONS FOR CONTROL OF RADIATION IN MISSISSIPPI

1500 Therapeutic Radiation Machines

1500.01 Scope and Applicability.

1. This section establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this section are in addition to, and not in substitution for, other applicable provisions of these regulations.

2. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by 1500.03.3.

1500.02 Definitions. As used in this section, the following definitions apply:

"Absorbed dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad (see "Rad").

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

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. Kerma is measured in the same unit as absorbed dose.

"Barrier" (See "Protective barrier").

"Beam axis" means the central ray of the useful radiation beam that passes through the isocenter and the source of radiation.

"Beam-limiting device" means a field defining collimator 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 scatter a beam of electrons in order 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.

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

"Contact therapy system" means a therapeutic radiation machine with a short source to skin distance (SSD), usually less than 5 centimeters.

"Detector" (See "Radiation detector").

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

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance 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 to1500.06.

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

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

"Half-value layer (HVL)" means the thickness of a specified material which attenuates under narrow beam conditions, x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material.

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

"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 smallest sphere through which the useful beam axis passes.

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

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

"Leakage radiation" means radiation emanating from the therapeutic source assembly except for the useful beam.

"Light field" means the area illuminated by light, being the locus of points at which the illumination exceeds a specific or specified level, simulating the radiation field.

"mA" means milliampere.

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

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

"Moving beam radiation therapy" means radiation therapy with continuous displacement of the radiation source relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy and rotational therapy.

"Nominal treatment distance" means:

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

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

"Patient" means an individual subjected to machine produced external beam radiation for the purposes of 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 which is performed to ensure that a previous calibration continues to be valid.

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

"Practical range of electrons" corresponds to classical electron range where the only contribution to dose is from bremsstrahlung x-rays. Precise definition may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" [Medical Physics 18(1): 73-109, Jan/Feb 1991] and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.

“Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

"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 are as follows:

a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.

b. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

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

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

"Radiation Therapy Physicist" means an individual qualified in accordance with 1500.03.4.

"Redundant dose monitoring combination" means a combination of two dose monitoring systems in which both systems are arranged to terminate irradiation in accordance with a preselected number of dose monitor units.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

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

"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.

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

"Simulator (radiation therapy simulation system)" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Source" means the region and/or material from which the radiation emanates.

"Source-skin distance (SSD)" means the distance measured along the central ray from the center of the front surface of the radiation source to the surface of the irradiated object or patient. [See also Target-skin distance]

"Stationary beam radiation therapy" means radiation therapy without displacement of the radiation source relative to the patient during irradiation.

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

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

"Target-skin distance (TSD)" means the distance measured along the central ray from the center of the front surface of the x-ray target to the surface of the irradiated object or patient. [See also Source-skin distance]

"Tenth-value layer (TVL)" means the thickness of a specified material which attenuates under broad beam conditions, 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 without the material.

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

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

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

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

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

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

"Wedge filter" means a filter which effects continuous change in transmission over all or a part of the radiation field.

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

1500.02 General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

1. Administrative Controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Agency. The registrant or the registrant's agent shall ensure that the requirements of Section 1500 are met in the operation of the therapeutic radiation machine(s).

2. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients.

3. Training for External Beam Radiation Therapy Authorized User. The registrant for any therapeutic radiation machine subject to 1500.06 or 1500.07 shall require the authorized user to be a physician who:

    a. Is certified in:

        i. Radiology or therapeutic radiology by the American Board of Radiology;

        ii. Radiation oncology by the American Osteopathic Board of Radiology;

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

        iv. Therapeutic Radiology by the Canadian Royal College of Physicians and Surgeons; or

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

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

            i. Radiation physics and instrumentation;

            ii. Radiation protection;

            iii. Mathematics pertaining to the use and measurement of radioactivity; and

            iv. Radiation biology.

        ii. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

            i. Review of the full calibration measurements and periodic quality assurance checks;

ii. Preparing treatment plans and calculating treatment times;

iii. Using administrative controls to prevent misadministrations;

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

v. Checking and using survey meters.

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

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

ii. Selecting proper dose and how it is to be administered;

iii. Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

iv. Postadministration follow-up and review of case histories.

c. Notwithstanding the requirements of 1500.03.3.a and 1500.03.3.b, the registrant for any therapeutic radiation machine subject to 1500.06 may also submit the training of the prospective authorized user physician for Agency review on a case-by-case basis.

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

4. Training for Radiation Therapy Physicist. The registrant for any therapeutic radiation machine subject to 1500.06 or 1500.07 shall require the Radiation Therapy Physicist to:

   a. Be registered with the Agency, under the provisions of Section 200 of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units.

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

      i. Therapeutic radiological physics;

      ii. Roentgen-ray and gamma-ray physics;

      iii. X-ray and radium physics; or

      iv. Radiological physics; or

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

   d. Be certified by the Canadian College of Medical Physics; or

   e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full-time training in therapeutic radiological physics and also 1 year of full-time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 1500.04.1, 1500.06.16, 1500.06.17, 1500.07.20, and 1500.07.21 under the supervision of a Radiation Therapy Physicist during the year of work experience; or

   f. Hold a bachelor's degree in a physical science and have completed 1 additional year of full-time training in therapeutic radiological physics and also 2 years of full-time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 1500.04.1, 1500.06.16, 1500.06.17, 1500.07.20, and 1500.07.21 under the supervision of a Radiation Therapy Physicist during the 2 years of work experience.

      Agency review of applicants in this category will only be on a case-by-case basis and additional information may be required for the Agency to determine if the applicant is qualified to function as a Radiation Therapy Physicist.

5. Qualifications of Operators

   a. Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology. ARRT Registered Radiologic Technologists, who have been working for two years or more in radiation therapy, will be allowed three years from the effective date of these regulations to fulfill the above listed requirements.[1]

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

6. Written safety procedures and rules shall be developed by a Radiation Therapy Physicist and shall be provided to each individual operating a therapeutic radiation machine, including any restrictions of the operating technique required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

7. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts who is specifically identified on the Certificate of Registration. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

8. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of Section 1500, these individuals are also subject to the requirements of 400.05, 400.10, and 400.18.

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

[1] "Essentials and Guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988.

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a. Report of acceptance testing;

b. Records of surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Section 1500, as well as the name(s) of person(s) who performed such activities;

c. Records of major maintenance and modifications performed on the therapeutic radiation machine after the effective date of these regulations, as well as the name(s) of person(s) who performed such services; and

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

10. Records Retention. All records required by Section 1500 shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in Section 1500. All required records shall be retained in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

1500.03 General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

1. Protection Surveys.

a. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with1500.08. The radiation protection survey shall be performed by, or under the direction of, a Radiation Therapy Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation:

i. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 400.06.1; and

ii. Radiation levels in unrestricted areas do not exceed the limits specified in 400.14.1 and 400.14.2.

b. In addition to the requirements of 1500.04.1.a, a radiation protection survey shall also be performed prior to any subsequent medical use and:

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

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

iii. After relocating the therapeutic radiation machine; or

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

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

d. If the results of the surveys required by 1500.04.1.a or 1500.04.1.b indicate any radiation levels in excess of the respective limit specified in1500.04.1.a, the registrant shall lock the control in the "OFF" position and not use the unit:

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

ii. Until the registrant has received a specific exemption from the Agency.

2. Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by 1500.04.1 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 400.14.1 of these regulations, before beginning the treatment program the registrant shall:

a. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 400.14.1 of these regulations;

b. Perform the survey required by 1500.04.1 again; and

c. Include in the report required by 1500.04.4 the results of the initial survey, a description of the modification made to comply with 1500.04.2.a, and the results of the second survey; or

d. Request and receive a registration amendment under 400.14.3 of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by 400.14.1 of these regulations.

3. Dosimetry Equipment.

a. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated for Cobalt-60 by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration;

b. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 1500.04.3.a. This comparison shall have been performed within the previous 12 months (6 months if the dosimetry system is an ionization chamber) and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 1500.04.3.a; and

c. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 1500.04.3.a and 1500.04.3.b, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision of, a Radiation Therapy Physicist.

4. Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for any therapeutic radiation machine subject to 1500.06 or 1500.07 shall furnish a copy of the records required in 1500.04.1 and 1500.04.2 to the Agency within 30 days following completion of the action that initiated the record requirement.

1500.04 Quality Management Program.

1. In addition to the definitions in 1500.02, the following definitions are applicable to a quality management program:

    a. "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.

    b. "Misadministration" means the administration of an external beam radiation therapy dose:

        i. Involving the wrong patient, wrong treatment modality, or wrong treatment site;

        ii. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

        iii. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

        iv. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

    c. "Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

    d. "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

2. Scope and Applicability. Each applicant or registrant subject to 1500.06 or 1500.07 shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

    a. Prior to administration, a written directive is prepared for any external beam radiation therapy dose;

        i. Notwithstanding 1500.05.2.a, a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

ii. Notwithstanding 1500.05.2.a, if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision; or

iii. Notwithstanding 1500.05.2.a, if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within 24 hours of the oral directive.

b. Prior to each administration, the patient's identity is verified, by more than one method, as the individual named in the written directive;

c. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

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

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

3. Submission of Quality Management Program

a. Each applicant subject to 1500.06 or 1500.07 shall submit a quality management program to the Agency as part of the application required by Section 200 of these regulations. The registrant shall implement the program upon issuance of a Certificate of Registration by the Agency.

b. Each existing registrant subject to 1500.06 or 1500.07 shall, within 30 days of the effective date of these regulations, submit to the Agency a written certification that a quality management program has been implemented, as well as a copy of said program.

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

a. Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program;

b. Conduct these reviews at intervals not to exceed 12 months;

c. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of 1500.05.2; and

d. Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for 3 years.

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

a. Assembling the relevant facts including the cause;

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

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

6. The registrant shall retain:

a. Each written directive; and

b. A record of each administered radiation dose, in an auditable form, for 3 years after the date of administration.

7. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The registrant shall furnish the modifications to the Agency within 30 days after the modification has been made.

8. The registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:

a. Notify the Agency by telephone no later than the next calendar day after discovery of the misadministration;

b. Submit a written report to the Agency within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the

patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

c. Notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he/she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;

d. Retain a record of each misadministration for 5 years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and

e. If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the Agency, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the Agency can be obtained from the registrant.

9. Aside from the notification requirement, nothing in 1500.05.8 affects any rights or duties of registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

1500.05 Therapeutic Radiation Machines of Less Than 500 kV.

1. Leakage Radiation. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

a. 5-50 kV Systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

b. >50 and <500 kV Systems. The leakage air kerma rate measured at a distance of 1 meter from the source in any direction shall not exceed 1

rad (1 cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (3O cGy) per hour.

2. Permanent Beam-Limiting Devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

3. Adjustable or Removable Beam-Limiting Devices.

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

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

4. Filter System. The filter system shall be so designed that:

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

   b. For equipment installed after the effective date of these regulations, an interlock system prevents irradiation if the proper filter is not in place;

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

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

5. (e) Tube Immobilization.

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

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

6. Source Marking. 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.

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

8. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

    a. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

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

    c. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

    d. The timer shall permit accurate presetting and determination of exposure times as short as 1 second;

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

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

    g. The timer shall be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

9. Control Panel Functions. The control panel, in addition to the displays required by other provisions in 1500.06 shall have:

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

    b. An indication of whether x-rays are being produced;

    c. Means for indicating x-ray tube potential and current;

    d. The means for terminating an exposure at any time;

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

f. For therapeutic radiation machines manufactured after the effective date of these regulations, a positive display of specific filter(s) in the beam.

10. Multiple Tubes. When a control panel may energize more than one x-ray tube:

a. It shall be possible to activate only one x-ray tube at any time;

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

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

11. Source-to-Skin Distance (SSD). There shall be a means of determining the central axis SSD to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.

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

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

14. Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of1500.09, the treatment room shall meet the following design requirements:

a. Aural Communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

b. Viewing Systems. Provision shall be made to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. The

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

15. Additional Requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

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

    b. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

    c. 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

    d. When any door referred to in 1500.06.15.c is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 100 mrad (1 mGy) per hour.

16. Full Calibration Measurements.

    a. Full calibration of a therapeutic radiation machine subject to 1500.06 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:

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

        ii. At intervals not exceeding 1 year; and

        iii. Before medical use under the following conditions:

            i. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be easily discerned; and

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

b. To satisfy the requirement of 1500.06.16.a, full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

c. A registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

17. Periodic Quality Assurance Checks.

a. Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to 8O1.X.6, which are capable of operation at greater than 150 kV.

b. To satisfy the requirement of 1500.06.17.a, quality assurance checks shall meet the following requirements:

i. The registrant shall perform quality assurance checks in accordance with written procedures established by the Radiation Therapy Physicist; and

ii. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified 1500.06.16.a. 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 1500.06.16.a shall be stated.

c. The cause for a parameter exceeding a tolerance set by the Radiation Therapy Physicist shall be investigated and corrected before the system is used for patient irradiation.

d. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiation Therapy Physicist's quality assurance check procedures, the system shall be recalibrated as required in 1500.06.16.a.

e. The registrant shall use the dosimetry system described in 1500.04.3 to make the quality assurance check required in1500.06.17.b.

f. The registrant shall have the Radiation Therapy Physicist review and sign the results of each radiation output quality assurance check at intervals not to exceed 1 month. The Radiation Therapy Physicist shall promptly notify the registrant in writing of the results of each radiation output quality assurance check. The registrant shall keep a copy of each written notification for 3 years.

g. Therapeutic radiation machines subject to 1500.06 shall have safety quality assurance checks of each external beam radiation therapy facility performed at intervals not to exceed 1 month.

h. To satisfy the requirement of 1500.06.17.g, safety quality assurance checks shall ensure proper operation of:

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

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

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

iv. Viewing systems; and

v. Electrically operated treatment room doors from inside and outside the treatment room.

i. The registrant shall promptly repair any system identified in 1500.06.17.h that is not operating properly.

j. The registrant shall maintain a record of each quality assurance check required by 1500.06.17.a and 1500.06.17.g for 3 years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

18. Operating Procedures.

a. The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 1500.06.16 and 1500.06.17 have been met;

b. Therapeutic radiation machines shall not be left unattended unless it is secured pursuant to 1500.06.9.e;

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

d. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

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

f. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. 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 400.06 of these regulations.

19. Possession of Survey Instrument(s). The registrant authorized to use a therapeutic radiation machine in accordance with 1500.06 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 1500.08.

1500.06 Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above).

1. Possession of Survey Instrument(s). A registrant authorized to use a therapeutic radiation machine in accordance with 1500.07 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 1500.08.

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

a. The absorbed dose rate 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 rate on

the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified;

b. Except for the area defined in 1500.07.2.a, the absorbed dose rate in tissue (excluding that from neutrons) at I meter from the electron path between the source and the target or electron window shall not exceed 0.5 percent of the absorbed dose rate in tissue on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified;

c. The neutron absorbed dose rate outside the useful beam shall be kept as low as practicable. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 800 square centimeters; and

d. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 1500.07.2.a through 1500.07.2.c for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

3. Leakage Radiation Through Beam-Limiting Devices.

a. Photon Radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that:

i. At the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeters by 10 centimeters radiation field.

ii. For fields of any size in which the maximum area shielded by the beam-limiting devices exceeds 500 square centimeters, the product of the average absorbed dose due to leakage radiation through the beam-limiting devices and the maximum area protectable by the beam-limiting devices shall not exceed one tenth (0.1) of the product of the maximum absorbed dose on the central axis of the useful beam and the area of the useful beam for a radiation field of 10 centimeters by 10 centimeters. All values of absorbed dose and area are referred to the nominal treatment distance.

b. Electron Radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam-limiting

device and electron applicator and other parts of the radiation head, such that the following limits apply:

i. The absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

i. An average of 2 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply in the area between a line 4 centimeters outside the periphery of the geometrical radiation field and the border of the maximum area protectable by the electron applicator; and

ii. A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply in the area between a line 2 centimeters outside the periphery of the geometrical radiation field and the border of the maximum area protectable by the electron applicator.

ii. For fields of any size in which the maximum area shielded by the electron applicator exceeds 1000 square centimeters, the product of the average absorbed dose due to leakage radiation through the electron applicators and the maximum area protectable by the electron applicators shall not exceed two tenths (0.2) of the product of the maximum absorbed dose on the central axis of the useful beam and the area of the useful beam for a radiation field of 10 centimeters by 10 centimeters. All values of absorbed dose and area are referred to the nominal treatment distance.

c. Measurement of Leakage Radiation.

i. Photon Radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two (2) tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently, and the leakage radiation from each set shall not exceed a maximum of 2 percent anywhere in the area protectable by that beam-limiting device.

ii. Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding 1 square centimeter suitably protected against

radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using 1 centimeter of tissue equivalent build up material.

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

4. Filters/Wedges.

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

b. If the absorbed dose rate information required by 1500.07.9 relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools;

c. For equipment manufactured after the effective date of these regulations which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

i. 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;

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

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

iv. An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

5. X-Ray Stray Radiation in the Useful Electron Beam. For equipment manufactured after the effective date of these regulations, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

6. Beam Monitors. All therapeutic radiation machines subject to 1500.07 shall be provided with beam monitoring devices. The sensors for this device shall be fixed in the useful beam during treatment, (or interlocked) to indicate the air kerma rate or dose rate.

    a. Equipment manufactured after the effective date of these regulations shall be provided with at least two independently powered integrating dose meters. Alternatively, a common power supply may be used if the production of radiation is terminated upon failure of any common element.

    b. Equipment manufactured on or before the effective date of these regulations shall be provided with at least one radiation detector. This detector shall be incorporated into a primary beam monitoring system;

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

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

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

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

        iv. For equipment manufactured after the effective date of these regulations, the design of the beam monitoring systems shall ensure that the:

            i. Malfunctioning of one system shall not affect the correct functioning of the secondary system; and

            ii. Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

        v. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of these regulations, each display shall:

            i. maintain a reading until intentionally reset;

            ii. have only one scale and no electrical or mechanical scale multiplying factors;

iii. utilize a design such that increasing dose is displayed by increasing numbers; and

iv. In the event of power failure, the beam monitoring information required in 1500.07.6.c.v.iii displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

7. Beam Symmetry.

   a. Bent-beam linear accelerators subject to 1500.07 shall be provided with auxiliary device(s) to monitor beam symmetry;

   b. The device(s) referenced in 1500.07.7.a shall be able to detect field asymmetry greater than 10 percent; and

   c. The device(s) referenced in 1500.07.7.a shall be configured to terminate irradiation if the specifications in 1500.07.7.b cannot be maintained.

8. Selection and Display of Dose Monitor Units.

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

   b. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

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

   d. For equipment manufactured after the effective date of these regulations, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

9. Air Kerma Rate/Absorbed Dose Rate. For equipment manufactured after the effective date of these regulations, a system shall be provided whose readings the air kerma rate or absorbed dose rate at a reference point in the treatment volume can be calculated. [The radiation detectors specified in 1500.07.6 may form part of this system.] In addition:

   a. The dose monitor unit dose rate shall be displayed at the treatment control panel;

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

c. For equipment manufactured after the effective date of these regulations, if the equipment can deliver under any conditions 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 400 rad (4 Gy).

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

a. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

b. If original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

c. For equipment manufactured after the effective date of these regulations, an indicator on the control panel shall show which monitoring system has terminated irradiation.

11. Termination Switches. 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.

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

13. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

    a. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

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

    c. For equipment manufactured after the effective date of these regulations, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary for the operator to reset the preset time selector; and

    d. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

14. Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

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

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

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

    d. An interlock system shall be provided to prevent irradiation with x-rays except to obtain a verification film, when electron applicators are fitted;

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

    f. 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.

15. Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

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

b. The measured energy value selected shall be displayed (MV for photons and MeV for electrons) at the treatment control panel before and during irradiation; and

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

16. Selection of Stationary Beam Radiation Therapy or Rotational Arc Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and rotational arc radiation therapy shall meet the following requirement:

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

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

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

d. 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;

e. Rotational arc radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement:

i. For equipment manufactured after the effective date of these regulations, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 15 degrees of arc differs by more than 20 percent from the selected value;

ii. For equipment manufactured after the effective date of these regulations, where gantry angle terminates the irradiation in rotational arc radiation therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle and total angle relationship;

iii. For equipment manufactured after the effective date of these regulations, an interlock shall be provided to prevent the gantry

moving more than 5 degrees beyond the selected angular limits during rotational arc radiation therapy; and

iv. For equipment manufactured after the effective date of these regulations, an interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise rotational arc radiation therapy.

f. Where the beam monitor system terminates the irradiation in rotational arc radiation therapy, the termination of irradiation shall be as required by 1500.07.10; and

g. For equipment manufactured after the effective date of these regulations, an interlock system shall be provided to terminate irradiation if movement of the gantry:

i. occurs during stationary beam radiation therapy; or

ii. stops during rotational arc radiation therapy unless such stoppage is a preplanned function.

17. Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of 1500.09, the following design requirements are made:

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

b. Control Panel. In addition to other requirements specified in Section 1500, the control panel shall also:

i. Be located outside the treatment room;

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

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

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

c. Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall

not be used for patient irradiation unless at least one viewing system is operational;

d. Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

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

f. Entrance Interlocks. Interlocks shall be provided such that all entrance doors must 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;

g. Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 400.14.1, and 400.14.2 of these regulations, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

h. Emergency Cutoff Switches. At least one (1) "scram button" or other 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 1500.07.11. 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;

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

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

18. Radiation Therapy Physicist Support.

a. The services of a Radiation Therapy Physicist shall be utilized in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiation Therapy Physicist shall be responsible for:

i. Full calibration(s) required by 1500.07.20 and protection surveys required by 1500.04.1;

ii. Supervision and review of dosimetry;

iii. Beam data acquisition and storage for computerized dosimetry, and supervision of its use;

iv. Quality assurance, including quality assurance check review required by 1500.07.21.e of these regulations;

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

vi. Perform calculations/assessments regarding misadministrations.

b. If the Radiation Therapy Physicist is not a full-time employee of the registrant, the operating procedures required by 11500.07.19 shall also specifically address how the Radiation Therapy Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Radiation Therapy Physicist can be contacted.

19. Operating Procedures.

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

b. Therapeutic radiation machines shall not be made available for medical use unless the requirements of 1500.04.1, 1500.07.20, and 1500.07.21 have been met;

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

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

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

20. Full Calibration Measurements.

a. Full calibration of a therapeutic radiation machine subject to 1500.07 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:

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

   ii. At intervals not exceeding 1 year; and

   iii. Before medical use under the following conditions:

      i. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be easily discerned; and

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

   iv. Notwithstanding the requirements of 1500.07.20.a.iii:

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

      ii. If the repair, replacement or modification does not affect all modes and/or energies, full calibration shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 1500.07.20.a.iii.a.

b. To satisfy the requirement of 1500.07.1.a, full calibration shall include all measurements required for annual calibration by American Association of Physicists in Medicine (AAPM) Report 13, "Physical Aspects of Quality Assurance in Radiation Therapy";

c. The registrant shall use the dosimetry system described in 1500.04.3 to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in 1500.07.20.b may then be made using a dosimetry system that indicates relative dose rates; and

d. The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

21. Periodic Quality Assurance Checks.

a. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 1500.07 at intervals not to exceed 1 week;

b. To satisfy the requirement of 1500.07.21.a, quality assurance checks shall include determination of all parameters for periodic quality assurance checks contained in American Association of Physicists in Medicine (AAPM) Report 13, "Physical Aspects of Quality Assurance in Radiation Therapy";

c. The registrant shall use a dosimetry system which has been intercompared within the previous 6 months with the dosimetry system described in 1500.04.3 to make the periodic quality assurance checks required in 1500.07.21.b;

d. The registrant shall perform periodic quality assurance checks required by 1500.07.21.a in accordance with procedures established by the Radiation Therapy Physicist;

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

i. The authorized user and Radiation Therapy Physicist shall be immediately notified if any parameter is not within its acceptable range. The therapeutic radiation machine shall not be made available for subsequent medical use until the Radiation Therapy Physicist has determined that all parameters are within their acceptable range;

ii. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or Radiation Therapy Physicist within 3 treatment days; and

iii. The Radiation Therapy Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 1 month;

f. Therapeutic radiation machines subject to 1500.07 shall have safety quality assurance checks of each radiation therapy facility performed at intervals not to exceed 1 week;

g. To satisfy the requirement of 1500.07.21.f, safety quality assurance checks shall ensure proper operation of:

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

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

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

iv. Viewing systems;

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

vi. At least one emergency power cutoff switch. 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. 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.

h. The registrant shall promptly repair any system identified in 1500.07.21.g that is not operating properly; and

i. A registrant shall maintain a record of each quality assurance check required by 1500.07.21.a and 1500.07.21.g for 3 years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

1500.07 Calibration and Check of Survey Instruments.

1. A registrant shall ensure that the survey instruments used to show compliance with this section have been calibrated before first use, annually, and following repair.

2. To satisfy the requirements of 1500.08.1, the registrant shall:

    a. Calibrate all required scale readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source;

    b. Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of scale rating; and

    c. Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

3. To satisfy the requirements of1500.08.2, the registrant shall:

    a. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

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

4. A registrant shall check each survey instrument for proper operation with the dedicated check source each day of use. The registrant is not required to keep records of these checks.

5. The registrant shall retain a record of each calibration required in 1500.08.1 for 3 years. The record shall include:

    a. A description of the calibration procedure; and

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

6. The registrant may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by 1500.08.5 shall be maintained by the registrant.

1500.08 Shielding and Safety Design Requirements.

1. Each therapeutic radiation machine subject to 1500.06 or 1500.07 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 400.06 and 400.14 of these regulations.

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 be submitted for Agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix A.

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Subpart 78

Section 1500

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

I. ALL THERAPEUTIC RADIATION MACHINES

A. Basic facility information including: name, telephone number and Agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

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

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

II. THERAPEUTIC RADIATION MACHINES UP TO 150 kV (PHOTONS ONLY)

In addition to the requirements listed in Section I. above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the make, model and serial number of the therapeutic radiation machine, as well as the maximum technique factors.

B. The maximum design workload for the facility, including the total anticipated number of exposures/films per day and/or week, as well as the type of treatment(s) or examination(s) which will be performed with the therapeutic radiation machine.

C. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the 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 external beam radiation therapy 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 400.06 of these regulations.

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

E. 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.

F. 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 door(s) 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.

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

III. THERAPEUTIC RADIATION MACHINES OVER 150 kV

In addition to the requirements listed in Section I. above, therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and/or electrons and/or protons or other subatomic particles shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including manufacturer, model number, and serial number of the therapeutic radiation machine, rad/gray or rem/sievert per minute at the isocenter and the energy(s) and type(s) of radiation produced [i.e., photon, electron]. The source to isocenter distance shall be specified.

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

C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s) and thickness 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.

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

E. 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.

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

G. 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.

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

IV. NEUTRON SHIELDING

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness and location of all neutron shielding material.

B. 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.

C. 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, identify the software used and the version/revision date.

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

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

V. REFERENCES

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

CERTIFICATION OF REGULATION

This is to certify that the above **PUT REGULATION NAME HERE** was adopted by the Mississippi State Board of Health on Put Date Here to become effective Put Date Here .

Brian W. Amy, MD, MHA, MPH
Secretary and Executive Officer