120.299: continued

(b) Notwithstanding the provisions in 105 CMR 120.299(B)(1)(c) and (d), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

(c) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

(C) Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with 105 CMR 120.299(A).

## 120.300: RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

### 120.301: Purpose and Scope

(A) Establish radiation safety requirements for persons using sources of radiation for industrial radiography,

(B) Apply to all licensees and registrants who use sources of radiation for industrial radiography,

(C) Apply to sealed radioactive sources and radiation machines, except for those regulations clearly applicable only to sealed radioactive sources; and,

(D) Supplement, but do not replace, other applicable requirements of 105 CMR 120.000.

### 120.302: Definitions

As used in 105 CMR 120.300, the following definitions apply:

Annual Refresher Safety Training means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal audits, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

ANSI means American National Standards Institute.

Associated Equipment means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (such as, guide tube, control tube, control cable (drive cable), removable source stop, "J" tube and collimator when it is used as an exposure head)

Cabinet Radiography means industrial radiography conducted in an enclosure or cabinet so shielded that doses to individual members of the public at every location on the exterior meet the limitations specified in 105 CMR 120.221(A).

Cabinet X-Ray System means an x-ray system with the x-ray tube installed in an enclosure which, independent of existing architectural structures except the floor on which it may be placed, is intended to:

(1) Contain at least that portion of a material being irradiated;
(2) Provide radiation attenuation; and,
(3) Exclude personnel from its interior during generation of x radiation.

Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities.

An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

120.302: continued

Certification means the authorization by the Massachusetts Radiation Control Program (Agency) of an individual to perform industrial radiography in the Commonwealth of Massachusetts.

Certification Identification (ID) Card means the document issued by the Agency to individuals who have completed the requirements stated in 105 CMR 120.320(B).

Certified Cabinet X-ray System means an x-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

Certified Industrial Radiographer means an individual who has met prescribed training and experience requirements and has passed an approved examination and is authorized by the Agency, pursuant to 105 CMR 120.321(H)(1), to perform industrial radiography.

Certifying Entity means an independent certifying organization or an Agreement State whose industrial radiographer certification program has been reviewed and found to have met the applicable parts of Appendix A of 10 CFR Part 34 for radioactive materials; or an independent certifying organization or radiation control agency whose x-ray/or combination certification requirements have been reviewed and found to be equivalent to criteria established by CRCPD.

Collimator means a small radiation shield of lead or other heavy metal which is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

Control Cable (Drive Cable) means the cable that is connected to the source assembly and used to drive the source from and return it to the shielded position.

Control Mechanism (Drive Mechanism) means a device that enables the source assembly to be moved from and returned to the shielded position. A drive mechanism is also known as a crank assembly.

Control Tube means a protective sheath for guiding the drive cable. The control tube connects the drive mechanism to the radiographic exposure device.

Crank-out Device means the cable, protective sheath, and hand crank used to move the sealed source from the shielded to the unshielded position to make an industrial radiographic exposure.

Enclosed Radiography means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.

Exposure Head (Source Stop) means a device that locates the gamma radiography sealed source in the selected working position. An exposure head is also known as a source stop.

Guide Tube means a flexible or rigid tube, such as a "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

Independent Certifying Organization means an independent organization that meets all of the applicable parts of Appendix A of 10 CFR Part 34 for radioactive materials, and/or comparable criteria for x-ray/combination established by CRCPD.

Industrial Radiography means the examination of the macroscopic structure of materials by nondestructive methods using sources of radiation derived from radioactive materials or radiation machines. For purposes of 105 CMR 120.300, industrial radiography does not include radiography performed with Lixiscopes or cabinet x-ray systems, nor does it include computed tomography or computer-based digital radiography in which the useful beam of radiation is collimated to detectors.

120.302: continued

Industrial Radiography -Radiation Machines means the process of performing industrial radiography using radiation producing machines.

Industrial Radiography -Radioactive Materials means the process of performing industrial radiography using radioactive materials.

Lay-barge Radiography means industrial radiography performed on any water vessel used for laying pipe.

Lixiscope means a portable light-intensified imaging device using iodine-125 as a sealed source.

Lock-out Survey means a radiation survey performed to determine that a sealed source is in its shielded position. The lock-out survey is performed before moving the radiographic exposure device or source changer to a new location or securing the radiographic exposure device or source changer.

Offshore Platform Radiography means industrial radiography conducted from a platform over a body of water.

Permanent Radiographic Installation means an installation or structure designed or intended for radiography and in which radiography is regularly performed and meets all the requirements of 105 CMR 120.319

Personnel Monitoring Badge means a whole body individual monitoring device that meets the requirements of 105 CMR 120.323(B).

Personal Supervision means supervision provided by a Certified Industrial Radiographer who is physically present at the site where sources of radiation and associated equipment are being used, visually evaluating the Radiographer Trainee and in such proximity that immediate assistance can be given if required.

Radiation Machine means any device capable of producing ionizing radiation except those which produce radiation only from radioactive material.

Radiation Safety Officer means an individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee and/or registrant and who meets the requirements of 105 CMR 120.380 and 120.005.

Radiographer means any individual who has successfully completed the training, testing and documentation requirements of 105 CMR 120.320(B), and who performs or personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of 105 CMR 120.000 and all license and/or certificate of registration conditions.

Radiographer Trainee means any individual who has successfully completed the training and testing requirements of 105 CMR 120.320(A) and who uses sources of radiation and related handling tools or radiation survey instruments under the personal supervision of a radiographer trainer.

Radiographic Exposure Device (Camera or Projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

Radiographic Personnel means any radiographer or radiographer trainee.

Sealed Source (Pill) means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

120.302: continued

Shielded Position means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

S-tube means a tube through which the radioactive source travels when inside a radiographic exposure device.

Shielded-room Radiography means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in 105 CMR 120.221(A).

Source Assembly (Pigtail) means a component to which the sealed source is affixed or in which the sealed source is contained. The source assembly includes the sealed source.

Source Changer means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

Source Stop *see* "Exposure Head".

Storage Area means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, machine, container, or sealed source.

Storage Container means a device other than a source changer in which sealed sources are stored.

Temporary Job Site means any location where industrial radiography is performed other than the location(s) listed in a specific license or certificate of registration.

Transport Container means a package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the U.S. Department of Transportation.

Underwater Radiography means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

120.303: Exemptions

(A) Certified cabinet x-ray systems are exempt from the requirements of 105 CMR 120.300 except for the requirements of 105 CMR 120.337(C) and (D).

(B) Industrial uses of lixiscopes are exempt from the rules in 105 CMR 120.300. Lixiscope use is regulated under 105 CMR 120.100.

120.305: Licensing and Registration Requirements for Industrial Radiographic Operations

The Agency will approve an application for a specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements:

(A) The applicant satisfies the general requirements specified in 105 CMR 120.020 for radiation machine facilities or 105 CMR 120.100 for radioactive material, as applicable, and any special requirements contained in 105 CMR 120.300;

(B) The applicant submits an adequate program for training radiographers and radiographer trainees that meets the requirements of 105 CMR 120.320;

(C) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

120.305: continued

(D) The applicant submits written operating and emergency procedures as described in 105 CMR 120.325;

(E) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer trainee at intervals not to exceed six months as described in 105 CMR 120.320(C);

(F) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

(G) The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 105 CMR 120.380(B) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures;

(H) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test and analyzing the samples. The description must include the:

(1) Methods of collecting the samples;
(2) Instruments to be used;
(3) Methods of analyzing the samples; and
(4) Pertinent experience of the person who will analyze the wipe samples.

(I) If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 105 CMR 120.314 and 120.323(B)(8);

(J) the applicant identifies and describes the location(s) of all field stations and permanent radiographic installations; and

(K) The applicant identifies the location(s) where all records required by 105 CMR 120.300 and other parts of 105 CMR 120.000 will be maintained.

120.310: Records of Receipt, Transfer, and Disposal of Sources of Radiation

Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sources of radiation. These records shall include the date, the individual making the record, the radionuclide, number of curies, and make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for Agency inspection until disposal is authorized by the Agency.

120.311: Limits on Levels of Radiation for Radiographic Exposure Devices, Source Changers, and Transport Containers

The maximum exposure rate limits for storage containers and source changers are 2 mSv/hr (200 mrem/hr) at any exterior surface, and 0.1 mSv/hr (10 mrem/hr) at one meter from any exterior surface with the sealed source in the shielded position.

120.312: Locking of Sources of Radiation, Storage Containers and Source Changers

(A) The control panel of each radiation machine shall be equipped with a locking device which will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or radiographer trainee, or an individual specifically authorized by the Agency.

120.312: continued

(B) Each radiographic exposure device must have a lock or outer lockable container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked and, if a keyed lock, the key removed at all times when not under the direct surveillance of a radiographer or radiographer trainee, or an individual specifically authorized by the Agency except at permanent radiograhic installations as stated in 105 CMR 120.319. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

(C) Each sealed storage container and source changer must have a lock or outer lockable container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked, and if a keyed lock the key removed when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer trainee.

(D) The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to 105 CMR 120.333(B).

120.314: Radiation Survey Instruments

(A) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by 105 CMR 120.300 and 120.225(A). Instrumentation required by 105 CMR 120.300 shall have a range from 0.02 mSv/hr (2 mrem/hr) through 0.01 Sv/hr (1 rem/hr).

(B) Each radiation survey instrument shall be calibrated:

(1) By a person licensed or registered by the Agency, another Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such service;

(2) At energies appropriate for the licensee's or registrant's use;

(3) At intervals not to exceed six months and after each instrument servicing other than battery replacement;

(4) To demonstrate an accuracy within plus or minus 20%; and,

(5) At two points located approximately ⅓ and ⅔ of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and for digital instruments, at three points between 0.02 and 10 mSv/hr (2 and 1,000 mrem/hr).

(C) Records of these calibrations shall be maintained for Agency inspection for five years after the calibration date.

(D) Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

120.315: Performance Requirements for Industrial Radiography Equipment

(A) Conformance with ANSI Standards. Equipment used in industrial radiographic operations shall meet the following minimum criteria:

(1) Each radiographic exposure device, source assembly, sealed source, and associated equipment shall meet the criteria set forth by ANSI N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone: (212) 642–4900.

(2) Radiation machines manufactured after January 10, 1992 used in industrial radiographic operations shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537- 1976, except accelerators used in industrial radiography.

(3) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of 105 CMR 120.315.

120.315: continued

(4) In *lieu* of 105 CMR 120.315(A)(1), equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

(5) Engineering analysis may be submitted by a licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the agency may find this an acceptable alternative to actual testing of the component in accordance with 105 CMR 120.315(A)(1).

(6) In addition to the requirements specified in 105 CMR 120.315(A)(1), the following requirements apply to radiographic exposure devices, source changers, source assemblies, sealed sources and associated equipment.

(a) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

1. Chemical symbol and mass number of the radionuclide in the device;
2. Activity and the date on which this activity was last measured;
3. Model or product code and serial number of the sealed source;
4. Name of the manufacturer of the sealed source; and,
5. Licensee's name, address, and telephone number.

(b) Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of 10 CFR part 71.

(c) Opening, repair or modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the Agency, the U.S. Nuclear Regulatory Commission (NRC) or Agreement State.

(7) Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(B) Labeling Storage, and Transportation

(1) The licensee may not use a radiographic exposure device source changer or a container to store radioactive material unless the radiographic exposure device source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, *i.e.*, magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

"CAUTION. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)" or "DANGER. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)."

(2) The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with 105 CMR 120.770

(3) Radiographic exposure devices, source changers, storage containers, and radiation machines, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

(4) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(5) The licensee’s or registrant’s name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use.

(C) Performance Requirements. In addition to the requirements specified in 105 CMR 120.315(A) and (B), the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for routine operations or to source changers:

120.315: continued

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.
(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.
(4) Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER -- RADIOACTIVE."

The label must not interfere with the safe operation of the exposure device or associated equipment.
(5) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.
(6) Guide tubes must be used when moving the source out of the device.
(7) An exposure head, endcap, or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.
(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.
(9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(D) Leak Testing and Replacement of Sealed Sources.
(1) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Agency, the Nuclear Regulatory Commission, or another Agreement State.
(2) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the Nuclear Regulatory Commission, or another Agreement State.
(3) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six months. The leak testing of the source must be performed using a method approved by the Agency, the Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerels (0.005 Ci) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis. The license shall maintain the records of the leak tests for inspection by the Agency for five years after it is made.
(4) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months.
(5) Any test conducted pursuant to 105 CMR 120.315(D)(1) and (2) which reveals the presence of 185 Bq (0.005 microcuries) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with regulations of the Agency. Within five days after obtaining results of the test, the licensee shall file a report with the Agency describing the equipment involved, the test results, and the corrective action taken.

120.315: continued

(6) Each exposure device using DU shielding and an "S" tube configuration shall be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Commission or an Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. Each licensee shall maintain records of leak testing of sealed sources and devices containing DU. The licensee shall retain each record for agency inspection for five years from the date of the leak test.

(7) An applicant or licensee who desires to conduct its own tests for leakage or contamination shall establish procedures to be followed when testing sealed sources for leakage or contamination and shall submit a description of such procedures to the Agency for approval. The description shall include the:

(a) Instrumentation to be used;
(b) Method of performing the tests; and
(c) Pertinent experience of the individual(s) who will perform the test.

120.316: Quarterly Inventory

(A) Each licensee or registrant shall conduct a physical inventory at intervals not to exceed three months to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license or registration.

(B) The licensee or registrant shall maintain records of the quarterly inventory in accordance with 105 CMR 120.364.

120.317: Utilization Logs

Each licensee and registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(A) A unique identification (*e.g.*, serial number) of each radiation machine, each radiographic exposure device in which a sealed source is located, and each sealed source;

(B) The name of the radiographer using the source of radiation;

(C) The location(s) where each source of radiation is used and dates of use; and,

(D) The date(s) each source of radiation is removed from storage and returned to storage. For fixed installations, the date(s) each source of radiation is energized or used and the number of exposures made. Utilization logs may be kept on form MRCP 120.300-2, Utilization Log, or on clear, legible records containing all the information required by 105 CMR 120.317(A) through (D). Copies of utilization logs shall be maintained for Agency inspection for five years. The records shall be kept at the location specified by the license or certificate of registration.

120.318: Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments

(A) The radiographer shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

(1) The equipment is in good working condition;
(2) The sources are adequately shielded; and,
(3) Required labeling is present.

120.318: continued

(B) Survey instrument operability must be performed using check sources or other appropriate means.

(C) If equipment problems are found, the equipment must be removed from service until repaired.

(D) Each licensee or registrant shall have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

(E) The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(F) Records of equipment problems and of any maintenance performed under 105 CMR 120.318 must be made in accordance with 105 CMR 120.366

120.319: Permanent Radiographic Installations

(A) Permanent radiographic installations shall have high radiation area entrance controls of the type described in 105 CMR 120.227(A)(2) and (3) and (B).

(B) Each entrance that is used for personnel access to the high radiation area shall have both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

(C) The control device or alarm system shall be tested for proper operation with a source of radiation at the beginning of each day of equipment use. The test shall include a check for the visible and/or audible signals. Entrance control devices that reduce the radiation level upon entry as described in 105 CMR 120.227(A)(1) shall be tested monthly. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee or registrant implements the continuous surveillance requirements of 105 CMR 120.331, ensures that radiographic personnel use an alarming ratemeter, and complies with the requirements of 105 CMR 120.330(B). Records of these tests shall be maintained for Agency inspection for five years.

## RADIATION SAFETY REQUIREMENTS

120.320: Training and Testing

(A) Radiographer Trainee Requirements. The licensee or registrant shall not permit any individual to act as a radiographer trainee until the individual

(1) has received copies of and instructions in the requirements described in 105 CMR 120.300 and the applicable sections of 105 CMR 120.100, 120.200, 120.750 , and applicable DOT regulations as referenced in 105 CMR 120.770, a copy of the license or certificate of registration issued to the licensee or registrant and copies of and instructions in the licensee's or registrant's operating and emergency procedures;

(2) has demonstrated an understanding of items in 105 CMR 120.320(A)(1) by successful completion of a written or oral examination, administered by the licensee or registrant;

(3) has been instructed in the use of the licensee's or registrant's sources of radiation, radiographic exposure devices, associated equipment, related handling tools and radiation survey instruments that may be employed in industrial radiographic assignments; and

120.320: continued

(4) has demonstrated, to the satisfaction of the licensee or registrant, an understanding of the instructions provided pursuant to 105 CMR 120.320(A)(2) and (3) as evidenced by successful completion of a written or oral test and a field examination on the subjects covered.

(B) Radiographer Requirements. The licensee or registrant shall not permit any individual to act as a radiographer until the individual:

(1) has completed a course of at least 40 hours on the applicable subjects outlined in 105 CMR 120.320(G). The course shall be one that has been accepted by the Agency, another radiation control agency or the NRC;

(2) has completed hands-on experience as a radiographer trainee under the personal supervision, as specified in 105 CMR 120.326, of one or more radiographers:

(a) Hands-on experience in addition to on the job training consisting of hands-on experience shall include at least minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines.

(b) Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of hands-on experience.

(3) has successfully completed within the last five years the appropriate agency-administerd examination as prescribed in 105 CMR 120.321. Or the appropriate examination of another certifying entity that affords the same or comparable certification standards of 105 CMR 120.320(B);

(4) Possess a current certification ID card issued in accordance with 105 CMR 120.321(H) or by another certifying entity that affords the same or comparable certification standards as those afforded by 105 CMR 120.320(B);

(5) Once an individual has completed the requirements of 105 CMR 120.320(B)(4), the licensee or registrant is not required to submit the documentation referenced in 105 CMR 120.320(B)(1) and (2).

(C) In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

(1) has received copies of and instruction in the requirements described in 105 CMR 120.300 and the applicable sections of 105 CMR 120.100, 120.200, 120.750 , and applicable DOT regulations as referenced in 105 CMR 120.770, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

(2) has demonstrated an understanding of items in 105 CMR 120.320(C)(1) by successful completion of a written or oral examination administered by the licensee or registrant;

(3) Has received training in the use and daily inspection of the registrant's radiation survey instruments, the registrant's radiation machines, or the licensee's radiographic exposure devices, associated equipment and related handling tools; and,

(4) Has demonstrated competence in the use of the equipment described in 105 CMR 120.320(C)(3) by successful completion of a practical examination administered by the licensee or registrant.

(D) The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(E) Except as provided in 105 CMR 120.320(E)(4), the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer trainee to ensure that the Agency's regulations, license or registration requirements, and operating and emergency procedures are followed. The inspection program must:

(1) Include observation of the performance of each radiographer and radiographer trainee during an actual industrial radiographic operation, at intervals not to exceed six months; and,

120.320: continued

(2) Provide that, if a radiographer or a radiographer trainee has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 105 CMR 120.320(C)(3) and the radiographer's assistant must demonstrate knowledge of the training requirements of 105 CMR 120.320(A)(3) by a practical examination administered by the licensee or registrant before these individuals can next participate in a radiographic operation.

(3) The Agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

(4) In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

(F) The licensee or registrant shall maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with 105 CMR 120.367.

(G) The licensee or registrant shall include the following subjects, as applicable, that are required in 105 CMR 120 320(B)(1):

(1) Fundamentals of radiation safety including:
  (a) Characteristics of gamma and x-radiation;
  (b) Units of radiation dose and quantity of radioactivity;
  (c) Significance of dose to include: radiation protection standards, biological effects of radiation dose, and case histories of industrial radiography incidents;
  (d) Levels of radiation from sources of radiation; and,
  (e) Methods of controlling radiation dose (time, distance, and shielding);

(2) Radiation detection instruments including:
  (a) Use, operation, calibration, and limitations of radiation survey instruments;
  (b) Survey techniques; and,
  (c) Use of personnel monitoring equipment to include as a minimum, film badges, TLDs OSLs, pocket dosimeters, alarming ratemeters and electronic personal dosimeters;

(3) Equipment to be used including:
  (a) Operation and control of radiographic exposure equipment, remote handling equipment, and storage and transport containers, including pictures or models of source assemblies (pigtails);
  (b) Operation and control of radiation machines;
  (c) Storage, control, and disposal of sources of radiation; and,
  (d) Inspection and maintenance of equipment.

(4) The requirements of pertinent state and federal regulations; and,

(5) Generic written operating and emergency procedures.

120.321: Applications and Examinations

(A) Any individual applying to the Agency for certification to perform industrial radiography shall:

(1) submit a complete and legible application on forms prescribed and furnished by the Agency.

(2) pay the appropriate non-refundable fee in accordance with 105 CMR 120.321(J) .

(3) meet the examination requirements set forth in 105 CMR 120.321(D) or satisfy the requirements for certification based on reciprocity as set forth in 105 CMR 120.321(K); and,

(4) provide evidence that the requirements for the given category and class for which certification is sought have been met.

(B) Application. The appropriate fee shall accompany the application when filing with the Agency. An application shall be deemed filed on the date that it is received by the Agency or on the date that it is postmarked by the United States Postal Service.

(C) Categories of Certification.

(1) The Agency shall certify individuals to perform industrial radiography as Certified Industrial Radiographer.

120.321: continued

(2) Each certification issued shall include a class endorsement for the type of industrial radiography authorized. Such class endorsements are limited to:
(a) Radioactive Materials;
(b) Radiation Machines; or
(c) Radioactive Materials and Radiation Machines.

(D) Examination Requirements. An individual who seeks certification as a Certified Industrial Radiographer must have passed, prior to application for certification, a written examination appropriate to the category of certification sought in accordance with 105 CMR 120.321(E). An individual seeking certification as a Certified Industrial Radiographer must pass, within 12 months prior to application for certification, a written examination appropriate to the category and class of certification sought in accordance with 105 CMR 120.321(G).

(E) Examination. The Agency shall accept results of examinations given by certifying entities as defined in 105 CMR 120.302.

(F) Approved Training Program. Industrial radiographer training programs shall be approved by the Agency. The Agency shall recognize training programs approved by certifying entities.

(G) Experience Requirements for Certification. Applicants for certification to perform industrial radiography shall have a minimum of experience appropriate to each category and class of industrial radiography as follows:

Certified Industrial Radiographer
(1) Radioactive Materials..... 200 hrs
(2) Radiation Machines ..... 120 hrs
(3) Both Radioactive Materials and Radiation ..... 320 hrs
Machines of which not less than 200 hours shall be with radioactive materials and not less than 120 hours shall be with radiation machines.

(H) Requirements for Issuance of Certification. The Agency shall certify in a category and class of industrial radiography any individual who has satisfied the following requirements: Certified Industrial Radiographer:
(1) Submitted an application for certification on a form prescribed by the Department;
(2) Submitted the application fee specified in 105 CMR 120.321(J)(1);
(3) Passed an examination as required by 105 CMR 120.321(D) or satisfies the requirements or certification based on reciprocity as set forth in 105 CMR 120.321(K); and,
(4) Completed the required hours of experience in industrial radiography as specified in 105 CMR 120.321(G) or satisfies the requirements for certification based on reciprocity as set forth in 105 CMR 120.321(K)

(I) Duration of Certification. The duration of certification issued by the Agency shall be:
Certified Industrial Radiographer ..... five years

(J) Fees.
(1) The application fees for certification shall be non-refundable and shall be as specified for Certified Idustrial Radiographer.
(2) The appropriate fees shall accompany the application when filing with the Agency.

(K) Reciprocity.
(1) The Agency shall issue certification to an applicant who has been certified in another state or jurisdiction provided that:
(a) The applicant holds a valid certification in the appropriate category issued by another state or jurisdiction;
(b) The jurisdiction that issued the certification is a certifying entity.
(c) The applicant presents a copy of the certification document issued by the other jurisdiction to the Agency; and
(d) The applicant submits the application fee in accordance with 105 CMR 120.321(J)(1).

120.321: continued

(2) Individuals who are certified by reciprocity shall either:
(a) Maintain the certification upon which the reciprocal certification was issued; or
(b) Satisfy the requirements of 105 CMR 120.321(H) prior to the expiration of the certification upon which reciprocal certification was issued.

(L) Requirements for Renewal of Certification.
(1) Prerequisites:
(a) An individual shall submit an application for re-examination and renewal of certification at least six months prior to the expiration date of certification. The Agency shall waive this requirement if the applicant satisfies the requirements of 105 CMR 120.321(A). An individual may not legally perform industrial radiography without valid certification.
(b) Each applicant shall submit a complete and legible application with the fee for renewal of certification in accordance with 105 CMR 120.321(A).
(2) Re-examination. Applicants for renewal of certification shall meet the requirements of 105 CMR 120.321(H)(1) including re-examination as described in 105 CMR 120.321(L)(1).
(3) An I.D. card shall be issued to each person who successfully completes the examination prescribed in 105 CMR 120.321(E).
(4 ) Each person's I.D. card shall contain his/her photograph. The Agency will take the photograph at the time the examination is administered.
(5) The I.D. card remains the property of the Commonwealth of Massachusetts and may be revoked or suspended under the provisions of 105 CMR 120.322.
(6) A fee of $15.00 shall be paid to the Agency for each replacement of a lost I.D. card.

120.322: Revocation or Suspension of an I.D. Card

(A) Any radiographer who violates 105 CMR 120.000 may be required to show cause at a formal hearing why his/her I.D. card should not be revoked or suspended.

(B) When an Agency order has been issued for an industrial radiographer to cease and desist from the use of radioactive material or revoking or suspending his/her I.D. card, the industrial radiographer shall surrender the I.D. card to the Agency until such time as the order is changed or the suspension expires.

(C) The Agency may act to suspend or revoke an individual's certification for any one or a combination of the following causes:
(1) Knowingly causing a material misstatement or misrepresentation to be made in the application for initial certification or renewal of certification if such misstatement or misrepresentation would impair the Agency's ability to assess and evaluate the applicant's qualifications for certification pursuant to 105 CMR 120.321;
(2) Knowingly falsifying records of employees when such falsification would impair the Agency's ability to assess and evaluate the applicant's qualifications for certification pursuant to 105 CMR 120.321;
(3) Willfully evading the statute or regulations pertaining to certification, or willfully aiding another person in evading such statute or regulations pertaining to certification;
(4) Exhibiting significant or repeated incompetence in the performance of industrial radiography duties;
(5) Performing industrial radiography in such a manner that requirements of 105 CMR 120.300 are violated resulting in a threat to health and safety of the individual, other workers or the public;
(6) Having had a similar certification suspended or revoked if the grounds for that suspension or revocation are the same or equivalent to one or more grounds for suspension or revocation as set forth in 105 CMR 120.016(C);
(7) Failure to maintain the out-of-state certification upon which certification by reciprocity was issued;

120.322: continued

(D) If, based upon any of the grounds in 105 CMR 120.322(C), the Agency determines that action to suspend or revoke certification is warranted, the Agency shall notify the individual and shall provide an opportunity for a hearing in accordance with 801 CMR 1.01 *et seq*. An opportunity for a hearing shall be provided before the Agency takes action to suspend or revoke an individual's certification unless the Agency finds that an immediate suspension of certification is required to protect against immediate danger to the public health or safety, in which case the Agency shall suspend an individual's certification pending a hearing.

(E) If the Agency finds that removal of certification is warranted, the usual action shall be a suspension of certification for up to one year. The term of suspension may be reduced by the Director of the Radiation Control Program, upon the recommendation of the hearing officer, if the hearing officer finds, based upon evidence presented to him/her during a hearing, that the conditions leading to the Preliminary Order for Suspension can be cured in less than one year. However, if the Agency finds that the causes are of a serious or continuous nature, such as past actions which posed an immediate threat to occupational or public health or safety, deficiencies that cannot be cured within one year, the Agency shall revoke the individual's certification.

(F) When an individual's certification is suspended or revoked, the individual shall surrender his/her certification document to the Agency until the termination of the suspension period or until reissuance of the certification.

(G) An individual whose certification has been revoked may seek reinstatement of certification by filing with the Agency a petition for reinstatement. Such petition may be filed one year or more after the beginning of the revocation period.

120.323: Personnel Monitoring

(A) The personnel monitoring program shall meet the applicable requirements of 105 CMR 120.200.

(B) When performing industrial radiographic operations the following shall apply:

(1) The licensee or registrant shall not permit an individual to act as a radiographer, or radiographer trainee unless each individual wears, on the trunk of the body at all times during radiographic operations, a combination of a direct-reading pocket dosimeter or an electronic personal dosimeter, an alarming ratemeter, and a personnel monitoring badge that is processed and evaluated by an accredited NVLAP processor. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(2) Pocket dosimeters shall meet the criteria in ANSI N13.5-1972 and shall have a range of zero to two millisieverts (zero to 200 millirems).

(3) Pocket dosimeters shall be recharged at the start of each work shift.

(4) Exposure indicated by each pocket dosimeter shall be recorded at the beginning of and at the end of each work shift.

(5) If an individual's pocket dosimeter is discharged beyond its range (*i.e*., goes "off-scale"), or if an individual's electronic personal dosimeter reads greater than two millisieverts (200 mrem), industrial radiographic operations by that individual shall cease and the individual's personnel monitoring badge shall be processed immediately. The individual shall not return to work with sources of radiation until a determination of his/her radiation exposure has been made.

(6) Each personnel monitoring badge shall be assigned to and worn by only one individual.

(7) If a personnel monitoring badge is lost or damaged, the worker shall cease work immediately until a replacement personnel monitoring badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel monitoring badge.

(8) Each alarm dosimeter must:

(a) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift.

(b) Emit an alarm signal at a preset dose rate of five mSv/hr (500 mr/hr).

(c) Require special means to change the preset alarm function; and

120.323: continued

(d) Be tested at periods not to exceed one year for correct response to radiation. Acceptable dosimeters must alarm within plus or minus 20% of the true radiation dose rate.

(C) Records of pocket dosimeter readings of personnel exposures shall be maintained for five years by the licensee or registrant for Agency inspection. If the dosimeter readings were used to determine external radiation dose (*i.e.*, no TLD, OSL or film badge exposure records exist), the records shall be maintained until the Agency authorizes disposal.

(D) Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20% of the true radiation exposure. Records of pocket dosimeter calibrations shall be maintained for five years by the licensee or registrant for Agency inspection.

(E) Processors of film badge, TLD and OSL devices must be certified by the NVLAP.

120.325: Operating and Emergency Procedures

(A) Operating and emergency procedures must include, as a minimum, instructions in the following:

(1) Appropriate handling and use of sources of radiation for industrial radiography so that no person is likely to be exposed to radiation doses in excess of the limits established in 105 CMR 120.200;
(2) Methods and occasions for conducting radiation surveys;
(3) Methods for posting and controlling access to radiographic areas;
(4) Methods and occasions for locking and securing sources of radiation;
(5) Personnel monitoring and the use of personnel monitoring equipment;
(6) Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in 105 CMR 120.770;
(7) The inspection, maintenance, and operability checks of radiographic exposure devices and associated equipment, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers and source changers;
(8) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;
(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by 105 CMR 120.385;
(10) The procedure for notifying proper persons in the event of an accident or incident;
(11) Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;
(12) Source recovery procedure if licensee will perform source recoveries;
(13) Maintenance of records; and,
(14) The procedures for calculating exposures as required by 105 CMR 120.323(B), when a personnel monitoring badge is lost or damaged.

(B) The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with 105 CMR120.367 and 105 CMR120.371.

120.326: Supervision of Radiographer Trainee

The radiographer's assistant shall be under the personal supervision of a radiographer when using sources of radiation, including radiation machines, radiographic exposure devices, associated equipment, or related handling tools, or while conducting radiation surveys required by 105 CMR 120.333(B) to determine that the sealed source has returned to the shielded position or the radiation machine has stopped producing radiation after an exposure. The personal supervision must include:

(A) The radiographer's physical presence at the site where the sources of radiation are being used;

120.326: continued

(B) The availability of the radiographer to give immediate assistance if required; and

(C) he radiographer's direct observation of the trainee's performance of the operations referred to in this section.

120.328: Conducting Industrial Radiographic Operations

(A) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 105 CMR120.320(C). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(B) All radiographic operations must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Agency.

(C) Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

(D) A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the Nuclear Regulatory Commission, or by another Agreement State.

120.331: Surveillance

(A) During each industrial radiographic operation, a radiographer or radiographer trainee shall maintain visual surveillance of the operation to protect against unauthorized entry into a radiation area or high radiation area, except where the high radiation area is equipped with a control device or alarm system as described in 105 CMR 120.227(A) or (B).

(B) Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal.

(C) The sealed source shall be secured and immobilized in its shielded position in the radiographic exposure device with an appropriate locking or latching mechanism each time the sealed source is returned to its shielded position.

(D) Notwithstanding the requirements of 105 CMR 120.243(A), High Radiation Area warnings may be placed at the periphery of the Radiation Area, or at the perimeter of access control.

120.332: Posting

Areas in which industrial radiography is being performed shall be posted conspicuously in accordance with 105 CMR 120.200 including:

(A) Radiation Areas. Each radiation area shall be posted conspicuously with a sign or signs displaying the radiation symbol and the words:

CAUTION (OR DANGER)

RADIATION AREA

Radiation Area means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

120.332: continued

(B) High Radiation Area. Each high radiation area shall be posted conspicuously with a sign or signs displaying the radiation symbol and the words:

CAUTION (OR DANGER)

HIGH RADIATION AREA

High Radiation Area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem) in one hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

(C) Ropes and/or barriers shall be used as necessary to prevent unauthorized entry to radiation areas.

(D) Notwithstanding the requirements of 105 CMR 120.242(A), each radiation area may be posted in accordance with 105 CMR 120.242(B), *i.e.*, High Radiation Area warnings may be placed at the periphery of the controlled area.

120.333: Radiation Surveys and Survey Records

(A) No radiographic operation shall be conducted unless at least one calibrated and operable radiation survey meter, as described in 105 CMR 120.314, is available and used at each site where radiographic exposures are made.

(B) A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device, including the source guide tube and collimator if provided, shall be surveyed.

(C) A survey shall be made of the storage area as defined in 105 CMR 120.302 whenever a radiographic exposure device is being placed in storage.

(D) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."

(E) (1) All potential radiation areas in which industrial radiographic operations are to be performed shall be posted in accordance with 105 CMR 120.332, based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (*i.e.*, with the sealed source in the exposed position) to confirm that 105 CMR 120.332 requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 105 CMR 120.221(A). Surveys to confirm the extent of the High Radiation Area, one mSv/hr (100 mr/hr), within the Radiation Area should not be undertaken.

(2) Each time the exposure device is relocated and/or the exposed position of the sealed source is changed, the requirements of 105 CMR 120.333(E)(1) shall be met.

(3) The requirements of 105 CMR 120.333(E)(2) do not apply to pipeline industrial radiographic operations when the conditions of exposure including, but not limited to, the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness remain constant.

(F) A survey with a radiation survey instrument shall be made to determine that the sealed source has been returned to its shielded position any time a radiographic exposure device is placed in storage. The entire circumference of the radiographic exposure device, including the source guide tube and collimator if provided, shall be surveyed.

(G) If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 105 CMR 120.221(A) at the exterior surface of the vehicle.

120.333: continued

(H) Surveys shall be performed on storage containers to ensure that radiation levels do not exceed the limits specified in 105 CMR 120.221(A). These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.

(I) A survey meeting the requirements of 105 CMR 120.333(F) shall be performed on the radiographic exposure device and the source changer after every sealed source exchange.

(J) Records shall be kept of the surveys required by 105 CMR 120.333(E), (F), (G), (H), (I) and 105 CMR 120.318(A). These records shall be maintained for Agency inspection for five years after completion of the survey. If a survey was used to determine an individual's exposure due to loss of personnel monitoring data, the records of the survey shall be maintained until the Agency authorizes disposal.

120.334: Records Required at Temporary Job Sites

Each licensee and registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for Agency inspection:

(A) The appropriate license or certificate of registration or equivalent document;

(B) The appropriate operating and emergency procedures;

(C) The applicable Agency rules;

(D) The survey records required pursuant to 105 CMR 120.333 for the period of operation at the site;

(E) The daily pocket dosimeter records for the period of operation at the site; and,

(F) The most recent records of instrument and device calibration and source leak tests. Acceptable records include tags or labels which are attached to the devices or survey instruments and decay charts for sources which have been manufactured within the last six months.

120.337: Special Requirements and Exemptions for Enclosed Radiography

(A) Systems for enclosed radiography, including shielded-room radiography and cabinet x-ray systems not otherwise exempted, shall comply with all applicable requirements of 105 CMR 120.300.

(B) Systems for enclosed radiography designed to allow admittance of individuals shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of 105 CMR 120.300, 120.221(A) and 120.222. Records of these evaluations shall be maintained for Agency inspection for five years after the evaluation.

(C) Certified cabinet x-ray systems are exempt from the requirements of 105 CMR 120.300 except that:

(1) The registrant shall comply with the requirements of 105 CMR 120.020 and 120.200.

(2) Tests for proper operation of interlocks must be conducted and recorded in accordance with 105 CMR 120.319. Records of these tests shall be maintained for Agency inspection until disposal is authorized by the Agency.

(3) The registrant shall perform an evaluation to determine compliance with 21 CFR 1020.40 at intervals not to exceed one year. Records of these evaluations shall be maintained for Agency inspection for five years after the evaluation.

(D) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 and no modification may be made to the system unless prior agency approval has been granted by the Agency pursuant to 105 CMR 120.020.

120.340: Underwater and Lay-barge Radiography

(A) Underwater and/or lay-barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with 105 CMR 120.360.

(B) In addition to the other requirements of 105 CMR 120.300, the following requirements apply to the performance of lay-barge radiography:

(1) Cobalt-60 sources with activities in excess of 740 GBq (20 Ci) (nominal) and iridium-192 sources with activities in excess of 3.70 TBq (100 Ci) (nominal) shall not be used in the performance of offshore platform or lay-barge radiography.

(2) Collimators shall be used for all industrial radiographic operations performed on lay-barges.

120.350: Prohibitions

(A) Industrial radiography performed with a sealed source that is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.

(B) Retrieval of disconnected sources or sources that cannot be returned by normal means to a fully shielded position or automatically secured in the radiographic exposure device, shall not be performed unless specifically authorized by a license condition.

## RECORDKEEPING REQUIREMENTS

120.360: Records for Industrial Radiography

Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license or registration.

120.361: Records of Receipt, Transfer, and Disposal of Sources of Radiation

(A) Each licensee or registrant shall maintain records showing the receipts, transfers and disposal of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for five years after it is made.

(B) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

120.362: Records of Radiation Survey Instruments

Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under 105 CMR 120.314 and retain each record for three years after it is made.

120.363: Records of Leak Testing of Sealed Sources and Devices Containing DU

Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels ( Ci). The licensee shall retain each record for five years after it is made or until the source in storage is removed.

120.364: Records of Quarterly Inventory

(A) Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by 105 CMR 120.316 and retain each record for five years.

120.364: continued

(B) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

120.365 Utilization Logs

Each licensee and registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(A) A unique identification (*e.g.*, serial number) of each radiation machine, each radiographic exposure device in which a sealed source is located, and each sealed source;

(B) The name of the radiographer using the source of radiation;

(C) The location(s) where each source of radiation is used and dates of use; and,

(D) The date(s) each source of radiation is removed from storage and returned to storage. For fixed installations, the date(s) each source of radiation is energized or used and the number of exposures made. Utilization logs may be kept on form MRCP 120.300-2, Utilization Log, or on clear, legible records containing all the information required by 105 CMR 120.365(A) through (D). Copies of utilization logs shall be maintained for Agency inspection for five years. The records shall be kept at the location specified by the license or certificate of registration.

120.366: Records of Inspections and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, associated Equipment, Source Changers, and Survey Instruments

(A) Each licensee or registrant shall maintain records specified in 105 CMR 120.318 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for three years after it is made.

(B) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

120.367: Records of Alarm System and Entrance Control Tests at Permanent Radiographic Installations

Each licensee or registrant shall maintain records of alarm system and entrance control device tests required by 105 CMR 120.319 and retain each record for three years after it is made.

120.368: Records of Training and Certification

Each licensee or registrant shall maintain the following records for five years:

(A) Records of training of each radiographer and each radiographer trainee. The record must include radiographer certification documents and verification of certification status, copies of written tests and the dates of oral and practical examinations administered by the licensee or registrant, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and,

(B) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

120.369: Copies of Operating and Emergency Procedures

Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license or registration. Superseded material must be retained for five years after the change is made.

120.370: Records of Personnel Monitoring

Each licensee or registrant shall maintain the following exposure records specified in 105 CMR 120.323:

(A) Direct reading dosimeter readings and yearly operability checks required by 105 CMR 120.323(B)(8) for five years after the record is made;

(B) Records of alarming ratemeter calibrations for five years after the record is made;

(C) Reports received from the personnel monitoring badge processor until the Agency terminates the license or registration; and,

(D) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel monitoring badges until the Agency terminates the license or registration.

120.371: Records of Radiation Surveys

Each licensee or registrant shall maintain a record of each survey as specified in 105 CMR 120.333(E). Each record must be maintained for five years after it is made.

120.372: Form of Records

Each record required by 105 CMR 120.360 through 120.372 must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

120.373: Location of Documents and Records

(A) Each licensee or registrant shall maintain copies of records required by 105 CMR 120.300 and other applicable Parts of 120.CMR 120.000 at the location specified in 105 CMR 120.305(K).

(B) Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

(1) The license or registration authorizing the use of sources of radiation;
(2) A copy of 105 CMR120.001 105 CMR120.200, 105 CMR120.300 and 105 CMR 120.750;
(3) Utilization logs for each source of radiation dispatched from that location as required by 105 CMR120.317;
(4) Records of equipment problems identified in daily checks of equipment as required by 105 CMR120.366(A);
(5) Records of alarm system and entrance control checks required by 105 CMR120.366, if applicable;
(6) Records of dosimeter readings as required by 105 CMR120.369;
(7) Operating and emergency procedures as required by 105 CMR120.325;
(8) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 105 CMR120.362;

120.373: continued

(9) Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 105 CMR120.369;
(10) Survey records as required by 105 CMR120.370, for the period of operation at the site;
(11) The shipping papers for the transportation of radioactive materials required by 105 CMR 120.770; and,
(12) When operating under reciprocity pursuant to 105 CMR120.100, a copy of the applicable State license or registration, or Nuclear Regulatory Commission license authorizing the use of sources of radiation

120.380: Radiation Safety Officer

The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

(A) The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:
(1) Completion of the training and testing requirements of 105 CMR 120.320(B);
(2) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and,
(3) Formal training in the establishment and maintenance of a radiation protection program.

(B) The Agency will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate experience and knowledge with respect to the establishment and maintenance of a radiation safety protection program.

(C) The specific duties of the RSO include, but are not limited to, the following:
(1) To establish and oversee operating, emergency, and ALARA procedures as required by 105 CMR 120.200, and to review them regularly to ensure that the procedures are current and conform to Agency regulations and to the license or registration conditions;
(2) To oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;
(3) To ensure that required radiation surveys and leak tests are performed and documented in accordance with 105 CMR 120.000, including any corrective measures when levels of radiation exceed established limits;
(4) To ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 105 CMR 120.200;
(5) To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;
(6) To investigate and report to the Agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;
(7) To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;
(8) To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
(9) To maintain records as required by 105 CMR 120.000.
(10) To ensure the proper storing, labeling, transport, and use of exposure devices and sources of radiation;
(11) To ensure that quarterly inventory and inspection and maintenance programs are performed in accordance with 105 CMR 120.316 and 120.318; and,
(12) To ensure that personnel are complying with 105 CMR 120.000, the conditions of the license or the registration, and the operating and emergency procedures of the licensee or registrant.

120.385: Notification of Incidents

(A) The Agency shall be notified of the loss or theft of sources of radiation, overexposures, and excessive levels in accordance with 105 CMR 120.281, 120.282, 120.283, and 120.288.

(B) In addition, each licensee or registrant shall submit a written report within 30 days to the Agency whenever one of the following events occurs:

(1) A source assembly cannot be returned to the fully-shielded position and properly secured;

(2) The source assembly becomes unintentionally disconnected from the drive cable;

(3) Any component critical to safe operation of the radiographic exposure device fails to properly perform its intended function; or,

(4) An indicator on a radiation-producing machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

(C) The licensee or registrant shall include the following information in each report submitted in accordance with 105 CMR 120.385(B):

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Manufacturer and model number of equipment involved in the incident;

(4) Location, time, and date of the incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence; and,

(7) Names and qualifications of personnel involved in the incident.

120.390: Reciprocity

All reciprocal recognition of licenses and certificates of registration by the Agency will be granted in accordance with 105 CMR 120.190 and 120.033.

120.400: X-RAYS IN THE HEALING ARTS

120.401: Purpose and Scope

105 CMR 120.400 establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with Commonwealth statutes to engage in the healing arts or veterinary medicine. The provisions of 105 CMR 120.400 are in addition to, and not in substitution for, other applicable provisions of 105 CMR 120.000.

120.402: Definitions

As used in 105 CMR 120.400, the following definitions apply:

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

Accessory Component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of 105 CMR 120.400 but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of 105 CMR 120.400 but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

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

120.402: continued

Air Kerma means kerma in air (*see* definition of Kerma)

Air Kerma Rate (AKR) means the air kerma per unit time.

Aluminum Equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

Approved Provider means a post-secondary institution of higher learning, a provider approved by the American Society of Radiologic Technologists (ASRT), a provider of Category I CME approved by the American Academy of Physician Assistants (AAPA), a provider accredited by the Accreditation Council for Continuing Medical Education (ACCME) or ACCME-recognized state medical society (SMS), a provider of Category 1 CME approved by the American Medical Association (AMA), or other recognized national continuing medical education approval body approved by the Agency.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation Block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[1] or other materials having equivalent attenuation.

Automatic Exposure Control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

Automatic Exposure Rate Control (AERC) means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.

Barrier (*See* Protective Barrier).

Beam Axis means a line from the source through the centers of the x-ray fields.

Beam-limiting Device means a device which provides a means to restrict the dimensions of the x-ray field.

Bone Densitometry System means a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients.

C-arm Fluoroscope means a fluoroscopic x-ray system in which the image receptor and x-ray tube housing assembly are connected or coordinated. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Cantilevered Tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

Cassette Holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film [imaging] cassette during an x-ray exposure.

Cephalometric Device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

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[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00% minimum aluminum, 0.12% copper.

120.402: continued

Certified Components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

Certified System means any x-ray system which has one or more certified component(s).

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

Coefficient of Variation or C means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[ \frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n - 1} \right]^{1/2}$$

where

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
$X_i$ = $i^{th}$ observation in sample.
n = Number of observations in sample.

Computed Tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Contact Therapy System means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five centimeters of the surface being treated.

Control Panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Contrast Scale (CS) means the change in the linear attenuation coefficient per CTN relative to water; that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:

$\mu_x$ = linear attenuation coefficient of the material of interest

$\mu_w$ = linear attenuation coefficient of water

$(CTN)_x$ = CTN of the material of interest

$(CTN)_w$ = CTN of water

Cooling Curve means the graphical relationship between heat units stored and cooling time.

CR means: Computed Radiography, an indirect type of imaging system. The receptor used within a CR cassette is called a photostimulable imaging plate and it absorbs the radiation exiting the patient. The exposed plate is processed in a CR reader, where the absorbed energy is extracted. The resultant latent image data is converted from an analog to a digital signal and a digital image is created.

120.402: continued

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

(a) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(b) Which is equipped with means for patient restraint; and

(c) Which is capable of rotation about its long (longitudinal) axis.

CT means computed tomography; the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

CT Condition of Operation means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 105 CMR 120.400.

CT Gantry means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

CT Number (CTN) means the number used to represent the x-ray attenuation associated with each elemental area of the CT image, that is:

$$CTN = \frac{k\,(\mu_x - \mu_w)}{\mu_w}$$

where:

$k$ = contrast (a value of 1,000 is assigned when the Hounsefield scale of CTN is used)

$\mu_x$ = linear attenuation coefficient of the material of interest

$\mu_w$ = linear attenuation of water

Cumulative Air Kerma means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

Dead-man Switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector (*See* Radiation Detector).

Diagnostic Source Assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic X-ray System means an x-ray system designed for irradiation of any part of the human (or animal) body for the purpose of diagnosis or visualization.

Diagnostic X-ray Imaging System means an assemblage of components for the generation, emission, and reception of x-ray and the transformation, storage, and visual display of the resultant x-ray image.

Direct Scattered Radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (*See* Scattered Radiation).

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).

120.402: continued

DR means Direct Radiography or Digital Radiography, is a form of x-ray imaging where digital x-ray sensors are used instead of traditional photographic film.

Elemental Area means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

Entrance Exposure Rate means the Exposure per unit time at the point where the center of the useful beam enters the patient.

Equipment (*See* X-ray Equipment).

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

Facility means the location within one building or vehicle and under the same administrative control at which one or more x-ray equipment systems are installed or located for the purpose of diagnosis or treatment.

Field Emission Equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to absorb preferentially selected radiations.

Fluoroscopic Air Kerma Display Devices means separate devices, subsystems, or components that provide the display of AKR and cumulative air kerma, respectively. They include radiation detectors, if any, electronic and computer components, associated software, and data displays.

Fluoroscopic Imaging Assembly means a subsystem in which x-ray photons produce a fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic Irradiation Time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopic Procedure means the production and display of serial x-ray images for the purpose of observing real-time motion of anatomical structures.

Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

Focal Spot (Actual) means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General Purpose Radiographic X-ray System means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad Shield means a protective barrier for the testes or ovaries.

Half-value Layer means the thickness of specified material which attenuate the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In 105 CMR 120.402: Half-value Layer, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

120.402: continued

Hand-held X-ray Equipment means x-ray equipment that is designed to be hand-held during operation.

Healing Arts Screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized by the Commonwealth of Massachusetts to prescribe such x-ray tests for the purpose of diagnosis or treatment. to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat Unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, *i.e.*, kVp x mA x second.

HVL (*See* Half-value Layer).

Image Intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image Receptor means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

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

Interventional Procedures means procedures that utilize imaging for guidance. Imaging includes, but is not limited to, fluoroscopy and CT.

Irradiation means the exposure of matter to ionizing radiation.

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged participles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

Kilovolts Peak (*See* Peak Tube Potential).

kV means kilovolts.

kVp (*See* Peak Tube Potential).

kWs means kilowatt second.

Last Image Hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral Fluoroscope means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

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

120.402: continued

Leakage Radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

(1) The useful beam; and,

(2) Radiation produced when the exposure switch or timer is not activated.

Leakage Technique Factors means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs, *i.e.*, ten milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(3) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Linear Attenuation Coefficient ($\mu$) means the quotient of dN/N by d1 when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traveling a distance d1 in a specific material.

Light Field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage Regulation means the difference between the no- load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100\ (V_n-V_l)/V_l$

where

$V_n$ = No-load line potential and

$V_l$ = Load line potential.

mA means milliampere.

mAs means milliampere second.

Maximum Line Current means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

Mobile X-ray Equipment (*See* X-ray Equipment).

Mode of Operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Movable Tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

120.402: continued

Multiple Tomogram System means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Nominal Tomographic Section Thickness means the full-width at half-maximum of the sensitivity profile taken at the center of the cross sectional volume over which x-ray transmission data are collected.

Nurse Practitioner means a person licensed as a Registered Nurse by the Massachusetts Board in Nursing pursuant to M.G.L. c. 112, § 74, who is authorized by such Board to practice in an advanced practice nursing role as a nurse practitioner pursuant to M.G.L. c. 112, § 80B, and 244 CMR 4.00: *The Practice of Nursing in the Expanded Role*.

NVLAP means National Voluntary Laboratory Accreditation Program.

Patient means an individual subjected to healing arts examination, diagnosis, or treatment.

PBL *See* 105 CMR 120.402: Positive Beam Limitation.

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

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

Phototimer means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (*See* Automatic Exposure Control).

Physician Assistant means a person licensed as a physician assistant by the Massachusetts Board of Registration in Physician Assistants pursuant to M.G.L. c. 112, § 9I.

PID (*See* "Position indicating device").

Portable X-ray Equipment (*See* X-ray Equipment).

Position Indicating Device means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a bean-limiting device.

Positive Beam Limitation means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

Post-secondary Institution of Higher Education means a degree granting institution duly accredited by an accrediting agency recognized by the United States Department of Education.

Practitioner of the Healing Arts means an individual licensed to practice healing arts by the Commonwealth of Massachusetts.

Primary Protective Barrier (*See* Protective Barrier).

Protective Apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

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

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

120.402: continued

(2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation.

Protective Glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Pulsed Mode means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than ½ second.

Qualified Medical Physicist means an individual is:

(1) Registered with the Agency, under the provisions of 105 CMR 120.026, as a provider of radiation services in the area of calibration and compliance surveys and,

(2) Is certified by the American Board of Radiology in:

(a) Therapeutic medical physics; or

(b) Diagnostic medical physics; or

(c) Nuclear medical physics; or

(3) Is certified by the American Board of Medical Physics; or

(4) Is certified by the Canadian College of Medical Physics; or

(5) Hold a master's or doctor's degree in physics, biophysics, radiological physics, Radiological Science, Nuclear Physics, health physics, or other catagory approved by the Agency.

Radiation Detector means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

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.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiography means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Radiographic Imaging System means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

Rated Line Voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated Output Current means the maximum allowable load current of the x-ray high-voltage generator.

Rating means the operating limits as specified by the component manufacturer.

Recording means producing a retrievable form of an image resulting from x-ray photons.

Reference Plane means a plane which is displaced from and parallel to the tomographic plane.

Routine means diagnostic procedures utilizing x-ray equipment that are performed at least weekly.

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomogram.

Scan Increment means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

Scan Sequence means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

120.402: continued

Scan Time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Scattered Radiation means radiation that, during passage through matter, has been deviated in direction (*See* Direct Scattered Radiation).

Secondary Dose Monitoring System means a system which will terminate irradiation in the event of failure of the primary system.

Secondary Protective Barrier (*See* Protective Barrier).

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.

SID (*See* Source-image Receptor Distance).

Single Tomogram System means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

Solid State X-ray Imaging Device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

Source means the focal spot of the x-ray tube.

Source-image Receptor Distance means the distance from the source to the center of the input surface of the image receptor.

Source-skin Distance (SSD) means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

Spot Film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film Device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

SSD means the distance from the source to the center of the entrant x-ray field in the plan tangent to the patient skin surface.

Stationary Tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Stationary X-ray Equipment (*See* X-ray Equipment).

Stray Radiation means the sum of leakage and scattered radiation.

Supervising Physician means a physician who holds a full license issued by the Board of Registration in Medicine and who supervises all professional activities of a physician assistant in accordance with 243 CMR 2.08 and 263 CMR 5.00. For the purposes of 105 CMR 120.405, a supervising physician shall meet the requirements of 120.405(K)(1)(a) or (b).

Technique Factors means the conditions of operation. They are specified as follows:

(1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

120.402: continued

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
(3) For CT equipment designed for pulsed operations, peaktube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and,
(5) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

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.

Tomogram means the depiction of the x-ray attenuation properties of a section through the body.

Tomographic Plane means that geometric plane which is identified as corresponding to the output tomogram.

Tomographic Section means the volume of an object whose attenuation properties are imaged in a tomogram.

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.

Tube Rating Chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

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 system to produce radiation.

Variable-aperture Beam-limiting Device means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible Area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray Exposure Control means a device, switch, button, or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

X-ray Control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimer, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray Equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:
(1) "Mobile X-ray Equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
(2) "Portable X-ray Equipment" means x-ray equipment designed to be hand-carried.
(3) "Stationary X-ray Equipment" means x-ray equipment which is installed in a fixed location.

120.402: continued

X-ray Field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is ¼ of the maximum in the intersection.

X-ray High-voltage Generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high voltage switches, electrical protective devices, and other appropriate elements.

X-ray System means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray Table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or buckey), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

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

120.403: General Requirements

(A) Administrative Controls.

(1) Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of 105 CMR 120.403(A)(1) are met in the operation of the x-ray system(s).

(a) An x-ray system which does not meet the provisions of 105 CMR 120.400 shall not be operated for diagnostic or therapeutic purposes, unless otherwise approved by the Radiation Control Program.

(b) Individuals who shall be operating the x-ray systems shall meet the requirements of 105 CMR 125.000: *Licensing of Radiologic Technologists*.

(c) A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

1. Patient's body size and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;
2. Type and size of the image receptor to be used;
3. Type and size of the image receptor combination to be used; if any
4. Source to image receptor distance to be used (except for dental intra-oral radiography); and
5. Type and location of placement of patient shielding (*e.g.* gonad, *etc.*) to be used.

(d) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures. These procedures shall be reviewed, updated, and documented annually by management.

(e) Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, and parents of pediatric patients whose presence might be required for the medical procedure or training shall be in the room or area during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

120.403: continued

2. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent. For interventional procedures, lead glasses shall be used.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

(f) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(g) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and

2. exposure of an individual for the purpose of healing arts screening except as authorized by 105 CMR 120.403(A)(1)(k).

(h) When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 105 CMR 120.403(A)(1)(d), shall list individual projections, specific patient conditions, or psychological development level where holding devices cannot be utilized;

2. Written safety procedures, as required by 105 CMR 120.403(A)(1)(d), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be instructed in personal radiation safety and protected as required by 105 CMR 120.403(A)(1)(e);

4. No individual shall be used routinely to hold film or patients;

5. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and,

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

(i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. An imaging system of appropriate speed consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Protective equipment including aprons, gloves, and shields shall be x-rayed annually for defects, such as holes, cracks, and tears to assure reliability and integrity. A record of this test shall be maintained for inspection by the Radiation Control Program. If such defect is found, equipment shall be replaced or removed from service until repaired or replaced.

4. Radiographic systems other than fluoroscopic, dental intra-oral, or veterinarian systems shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

5. Mammographic procedures shall only be performed on special purpose mammographic equipment.

6. Mobile or portable radiographic systems shall only be used for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

120.403: continued

7. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

a. Be positioned properly, *i.e*., tube facing the right direction, and grid centered to the central ray;

b. If the grid is of the focused type, be of the proper focal distance for the SIDs being used.

(j) All occupationally exposed individuals are subject to the requirements of 105 CMR 120.211, 120.215, 120.217 and 120.218.

(k) If the facility ceases to operate, the Registrant or Responsible person of the facility must notify the Radiation Control Program within 15 days. Included in this notification, is the name and address of the person who disposed of the x-ray unit.

(2) The registrant of the facility shall ensure that the equipment is in safe operating condition:

(a) when it is first installed and prior to use on patients;

(b) after any major changes or replacement of parts and prior to use on patients:

(c) by having physics surveys, calibrations and preventative maintenance such physics surveys and preventative maintenance shall be made annually:

1. The physics surveys shall be performed by a qualified medical physicist;

2. The preventative maintenance or calibration shall be performed by a registered service provider as specified in 105 CMR 120.026.

(d) Physics surveys shall be reviewed and signed within a reasonable time of completion of the tests but no longer than 30 days of completion of the tests by a qualified medical physicist and a responsible person at the facility or responsible physician, and any necessary corrective action shall be implemented within 30 days.

(e) Records of calibrations and preventative maintenance shall be maintained at the facility for three years.

(3) Information and Maintenance Record and Associated Information. The registrant of a facility shall maintain the following information for each x-ray system for inspection by the Radiation Control Program:

(a) Model and serial numbers of all major components, and user's manuals for those components;

(b) Records of installation, surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after the effective date of 105 CMR 120.000 with the names of persons who performed such services;

(c) A copy of the service providers certificate of registration shall be maintained by the facility.

(d) A scale drawing provided by a registered service provider or qualified medical physicist of the room in which a stationary x-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

1. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

2. The type and thickness of materials, or lead equivalency, of each protective barrier; and,

(e) A copy of all correspondence with this Radiation Control Program regarding that x-ray system.

(4) X-ray Utilization Log. Each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

(5) Radiograph and Record Retention. Radiographs shall be retained for at least a minimum of five years following last visit of the patient. The written reports become a part of the patient's medical record and are to be retained for 20 years following last visit of patient.

(6) Quality Assurance Program.

(a) All registrants of diagnostic x-ray imaging equipment shall establish and maintain a quality assurance program consisting of quality control assessments addressing at least the following items:

120.403: continued

1. Written standard operating procedures on radiation protection and the practice of radiologic technology reviewed, updated, and documented annually by management.
2. Employee review and written acknowledgement of standard operating procedures and policies on radiation protection and the practice of radiologic technology shall be documented annually.
3. Credentialling of practitioners, medical physicists, and x-ray equipment operators.
4. Film Processing equipment:
   a. Compliance with 105 CMR 120.403(C);
   b. Film processor performance to include medium density, density difference, and base + fog;
   c. Darkroom fog;
5. Radiographic equipment:
   a. Compliance with performance standards in 105 CMR 120.404 and 120.406;
   b. Entrance skin exposure rates of selected patient examinations;
   c. Image printing and viewing equipment;
   d. Measurement of low and high contrast resolution; and
   e. Radiation protection.
6. Fluoroscopic equipment:
   a. Compliance with performance standards in 105 CMR 120.405;
   b. Entrance skin exposure rates of selected patient examinations;
   c. Image printing and viewing equipment;
   d. Measurement of low and high contrast resolution; and
   e. Radiation protection.
7. Computerized tomography equipment:
   a. Compliance with performance standards in 105 CMR 120.409;
   b. CT number;
   c. Low contrast and high contrast resolution;
   d. Dosimetry of selected patient examinations to include pediatric patients if applicable;
   e. Image printing and viewing equipment; and
   f. Radiation protection.
8. Bone densitometry equipment: Compliance with requirements in 105 CMR 120.410.
9. Structural shielding for new facilities with x-ray equipment:
   a. Pre-construction shielding design and evaluation; and
   b. Post-construction radiation protection survey.
10. Structural shielding for modifying use or equipment in existing facility:
   a. Re-evaluation of shielding design; and
   b. Post-modification radiation protection survey.

(b) The registrant of a facility shall assign qualified personnel to fully implement the quality assurance program.

(c) Quality control assessments may be assigned to qualified personnel who possess the requisite training and/or experience.

(d) Quality control assessments shall be conducted by or under the direction of, a qualified medical physicist.

(e) The registrant of a facility and/or qualified medical physicist shall determine the frequency of quality control tests but shall not be less stringent than the manufacturers recommendations.

(f) The quality assurance program shall be in written form and available for review by the Agency.

(g) Equipment used for compliance with the provisions of 105 CMR 120.403(6) shall be properly calibrated and maintained in accordance with accepted professional standards.

105 CMR 120.403(A)(6) does not pertain to quality assurance for mammography equipment *see* 105 CMR 127.000.

120.403: continued

(7) Healing Arts Radiologic Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Radiation Control Program. When requesting such approval, that person shall submit the information outlined in 105 CMR 120.421: *Appendix B*. If any information submitted to the Radiation Control Program becomes invalid or outdated, the Radiation Control Program shall be immediately notified.

(B) Plan Review.

(1) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Radiation Control Program for review and approval. The required information is denoted in 105 CMR 120.420: *Appendix A* and 105 CMR 120.422: *Appendix B*, unless specifically exempted.

(2) The Radiation Control Program may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 105 CMR 120.211, 120.217, 120.218 and 120.221.

(C) X-ray Film Processing Facilities and Practices.

(1) Each installation using a radiographic x-ray system and using analog image receptors (*e.g*. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(a) Manually developed film:

1. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

2. The temperature of solutions in the tanks shall be maintained within the range of 60ºF to 80ºF (16ºC to 27ºC). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

120.403: continued

| Time-Temperature Chart | | |
|---|---|---|
| Thermometer Reading (Degrees) | | Minimum Developing Time (Minutes) |
| °C | °F | |
| 26.7 | 80 | 2 |
| 26.1 | 79 | 2 |
| 25.6 | 78 | 2½ |
| 25.0 | 77 | 2½ |
| 24.4 | 76 | 3 |
| 23.9 | 75 | 3 |
| 23.3 | 74 | 3½ |
| 22.8 | 73 | 3½ |
| 22.2 | 72 | 4 |
| 21.7 | 71 | 4 |
| 21.1 | 70 | 4½ |
| 20.6 | 69 | 4½ |
| 20.0 | 68 | 5 |
| 19.4 | 67 | 5½ |
| 18.9 | 66 | 5½ |
| 18.3 | 65 | 6 |
| 17.8 | 64 | 6½ |
| 17.2 | 63 | 7 |
| 16.7 | 62 | 8 |
| 16.1 | 61 | 8½ |
| 15.6 | 60 | 9½ |

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

120.403: continued

(b) Automatic processors and other closed processing systems:

(1) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

| Developer Temperature | | Minimum Immersion Time[a/] |
|---|---|---|
| °C | °F | Seconds |
| 35.5 | 96 | 19 |
| 35.0 | 95 | 20 |
| 34.5 | 94 | 21 |
| 34.0 | 93 | 22 |
| 33.5 | 92 | 23 |
| 33.0 | 91 | 24 |
| 32 .0 | 90 | 25 |
| 31.5 | 89 | 26 |
| 31.0 | 88 | 27 |
| 30.5 | 87 | 28 |
| 30.0 | 86 | 29 |
| 29.5 | 85 | 30 |

[a/] Immersion time only, no crossover time included.

2. The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

(c) Processing deviations from the requirements of 105 CMR 120.403(C)(1) shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (*e.g.*, extended processing, and special rapid chemistry). The requirements of 105 CMR 120.403(C)(1)(c) apply only to film processors routinely used in processing diagnostic x-ray images.

(d) Quality Assurance tests for the processor shall be performed on days being used.

(e) Test tools for quality assurance tests for the processor shall include the following:

1. Densitometer
2. Sensitometer
3. Thermometer
4. Film

(f) Daily film processor quality assurance tests shall include: Checking solution temperatures.

1. The developer temperature shall be as recommended by the film manufacturer.
2. Mercury thermometers are prohibited for determining solution temperatures.

(g) Determination and recording of the speed step. Maximum control limits shall not exceed ± 0.15 optical density (OD).

(h) Calculation and recording of the contrast index or density difference. Maximum control limits shall not exceed ± 0.15 optical density (OD).

(i) Measuring and plotting the Base + Fog. Maximum base plus fog density shall not exceed 0.25 optical density (OD).

(j) Chemistry replenishment rates shall be measured and recorded semi-annually.

(k) Processor sensitometric tests results including speed index, contrast index, and base plus fog shall be plotted on control charts.

(l) Operating levels and control limits for processor quality assurance tests shall be indicated on the control chart.

(m) Quality assurance records shall be maintained for a minimum of 24 months and readily available for review by representatives of the Department.

(n) Each facility shall take corrective action when Quality Assurance test do not meet the requirements in 105 CMR 120.403(C).

120.403: continued

(2) Other Requirements:

(a) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(b) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

1. Quality assurance tests for darkroom integrity shall be performed at least semi-annually.
2. Each facility shall use pre-exposed film for performing quality assurance tests.
3. No smoking or eating is permitted in the darkroom.
4. The darkroom shall be kept free of dust.
5. Counter tops, floors, and processing feed trays shall be cleaned daily before any films are handled or processed.

(c) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(d) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(e) Film cassettes and intensifying screens shall be kept free of artifacts and shall be cleaned regularly and replaced as necessary to best assure radiographs of good diagnostic quality.

(f) Screens shall be cleaned at intervals not to exceed one month with a screen cleaner recommended by the screen manufacturer. A copy of this requirement shall be kept in the darkroom.

(g) Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

(h) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

120.404: General Requirements for All Diagnostic X-ray Systems

In addition to other requirements of 105 CMR 120.400, all diagnostic x-ray systems shall meet the following requirements:

(A) Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(B) Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(C) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgen (25.8 μC/kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(D) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgen (0.516 μC/kg) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

120.404: continued

(E) Beam Quality.

(1) Half-value Layer.

(a) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

(b) For capacitor energy storage equipment, compliance with the requirements of 105 CMR 120.404(E) shall be determined with the system fully charged and a setting of ten mAs for each exposure.

(c) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

(2) Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 105 CMR 120.404(E)(1) is in the useful beam for the given kVp which has been selected.

Specified Dental Systems \1\

TABLE I

| X-Ray Tube Voltage (kilovolt peak) | | | | |
|---|---|---|---|---|
| Design Operating Range | Measured Operating Potential | Minimum HVL (mm in Aluminum) | | |
| | | Specified Dental Systems[1] | Other X-Ray Systems[2] | Other X-Ray Systems[3] |
| Below 51 | 30 | 1.5 | 0.3 | 0.3 |
| | 40 | 1.5 | 0.4 | 0.4 |
| | 50 | 1.5 | 0.5 | 0.5 |
| 51 to 70 | 51 | 1.5 | 1.2 | 1.3 |
| | 60 | 1.5 | 1.3 | 1.5 |
| | 70 | 1.5 | 1.5 | 1.8 |
| Above 70 | 71 | 2.1 | 2.1 | 2.5 |
| | 80 | 2.3 | 2.3 | 2.9 |
| | 90 | 2.5 | 2.5 | 3.2 |
| | 100 | 2.7 | 2.7 | 3.6 |
| | 110 | 3.0 | 3.0 | 3.9 |
| | 120 | 3.2 | 3.2 | 4.3 |
| | 130 | 3.5 | 3.5 | 4.7 |
| | 140 | 3.8 | 3.8 | 5.0 |
| | 150 | 4.1 | 4.1 | 5.4 |

[1] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to 105 CMR 120.404 and manufactured before June 10, 2006.

[3] All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to 105 CMR 120.404 and manufactured on or after June 10, 2006.

120.404: continued

(F) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

(G) Mechanical Support of Tube Housing Assembly. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

(H) Technique Indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic Exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 105 CMR 120.404(H)(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(I) Maintaining Compliance Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

(J) Locks. All positioning locking, holding, and centering devices on x-ray systems components and systems shall function as intended.

120.405: Fluoroscopic X-ray Systems

Fluoroscopic X-ray Systems shall be installed and maintained to comply with the Federal Performance Standard for Fluoroscopic Equipment, 21 CFR 1020.32 and shall also meet the following requirements except 21 CFR 1020.32 shall prevail should there be a conflict.

(A) Limitation of Useful Beam.

(1) Primary Barrier.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

(b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(c) Radiation therapy simulation systems shall be exempt from 105 CMR 120.405(A) provided the systems are intended only for remote control operation.

(2) Fluoroscopic Beam Limitation.

(a) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3% of the SID. The sum of the excess length and the excess width shall be no greater than 4% of the SID.

(b) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

(c) For uncertified fluoroscopic systems without a spot film device, the requirements of 120.405(A)(2)(a) apply.

1. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

2. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;

120.405: continued

3. If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;

4. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and,

5. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(d) For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

1. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80% of the area of the x-ray field overlaps the visible area of the image receptor; or

2. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two cm.

(3) Spot-film Beam limitation. Spot-film devices shall meet the following requirements:

(a) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3% of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4% of the SID;

(c) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters by five centimeters;

(d) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2% of the SID; and,

(e) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic x-ray field size adjustments required in 105 CMR 120.405(A)(2), that means:

(a) Shall be designed for use only in the event of system failure;

(b) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and,

(c) Shall be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

(B) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

120.405: continued

(C) Air Kerma Rates.

(1) Fluoroscopic Equipment Manufactured Before May 19, 1995.

(a) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in AKR in excess of 88 mGy per minute (ten roentgens) per minute at the point where the center of the useful beam enters the patient, except:

1. During recording of fluoroscopic images; or

2. When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an AKR in excess of ten roentgens (88 mGy) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in AKR in excess of 44 mGy (five roentgens) per minute at the point where the center of the useful beam enters the patient, except:

1. During recording of fluoroscopic images; or

2. When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(c) Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an AKR in excess of 88 mGy (ten roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except:

1. During recording of fluoroscopic images; or

2. When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current which shall result in an AKR in excess of 88 mGy (ten roentgens) per minute at the point where the center of the useful beam enters the patient, unless high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(2) Fluoroscopic Equipment Manufactured On or After May 19, 1995.

(a) Shall be equipped with automatic exposure rate control if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (five R/min exposure rate) at the measurement point specified in 105 CMR 120.405(C)(3). Provision for manual selection of technique factors may be provided.

(b) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (ten R/min exposure rate) at the measurement point specified in 105 CMR 120.405(C)(3).

(c) Exceptions:

1. For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

2. For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

120.405: continued

3. When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in 105 CMR 120.405(C)(3). Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

(3) Compliance with the requirements of 105 CMR 120.405(C) shall be determined as follows:

(a) If the source is below the table, the AKR shall be measured one centimeter above the tabletop or cradle.

(b) If the source is above the table, the AKR shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(c) For a C-arm type of fluoroscope, the AKR shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(d) For a lateral type fluoroscope, the air kerma rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

(e) In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

(4) The registrant of a facility or responsible person at the facility shall have a qualified medical physicist perform periodic measurement of AKR for both typical and maximum values as follows:

(a) Such measurements shall be made annually or after any maintenance of the system which might affect the AKR;

(b) If the fluoroscope does not display the AKR of the current patient in view of the operator when the fluoroscopy trigger is depressed, results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 105 CMR 120.403(A)(2)(b). The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;

(c) Conditions of periodic measurement of typical AKR are as follows:

1. The measurement shall be made under the conditions that satisfy the requirements of 105 CMR 120.405(C)(1)(c);

2. The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use for an abdominal patient;

3. The x-ray system that incorporates automatic Exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of 105 CMR 120.405(C)(1)(e)3.; and

(d) Conditions of periodic measurement of maximum AKR are as follows:

1. The measurement shall be made under the conditions that satisfy the requirements of 105 CMR 120.405(C)(1)(c);

2. The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum AKR;

3. The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attentuative material placed in the useful beam to produce the maximum AKR of the system.

120.405: continued

(D) Barrier Transmitted Radiation Rate Limits.

(1) The AKR due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgen (0.516 μC/kg) per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of AKR.

(2) Measuring Compliance of Barrier Transmission.

(a) The AKR due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(b) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(c) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

(d) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(e) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of AKR and between this point and the input surface of the fluoroscopic imaging assembly.

(E) Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

(F) Source-to-skin Distance.

(1) Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in 105 CMR 120.405(D)(1), provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.

(2) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in 105 CMR 120.405(F)(2), provisions may be made for operation at shorter source-skin distances but in no case less than ten cm.

(G) Fluoroscopic Timer.

(1) Fluoroscopic Equipment Manufactured Before June 10, 2006:

(a) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(2) For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

(a) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in 105 CMR 120.405(G)(2). The following requirements apply:

1. When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds.

2. The fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset.

120.405: continued

3. Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

(b) A signal audible to the fluoroscopist shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.

(H) Control of Scattered Radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(a) Is at least 120 centimeters from the center of the useful beam; or

(b) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 105 CMR 120.403(A)(1)(e).

(3) The Agency may grant exemptions to 105 CMR 120.405(H)(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption. *See* 105 CMR 120.423: *Appendix D* for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

(I) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 105 CMR 120.405(A), (C), (D) and (G) provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and,

(2) Systems which do not meet the requirements of 105 CMR 120.405(G) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(J) Spot film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) modes shall meet the exposure reproducibility requirements when operating in the spot film mode.

(K) Operator Qualifications.

(1) The Registrant of a facility shall ensure that only the following health care providers shall be allowed to operate fluoroscopic x-ray systems:

(a) Licensed physicians who are board-certified in radiology;

(b) Licensed physicians who are not board-certified in radiology provided that they have been trained in the following subjects:

1. Principles and operation of the fluoroscopic x-ray system;
2. Biological effects of x-ray;
3. Principles of radiation protection;
4. Fluoroscopic outputs;
5. High level control options;
6. Dose reduction techniques for fluoroscopic x-ray systems; and
7. Application requirements of 105 CMR 120.000.

(c) Radiologic technologists who are licensed in accordance with 105 CMR 125.000 and have been trained in the safe use of fluoroscopic x-ray systems; and

(d) Physician assistants who are licensed in accordance with M.G.L. c. 112, § 9I, and 263 CMR 3.00: *Registration of Individual Physician Assistants*, and who meet the requirements of 105 CMR 120.405(K)(2).

(2) The Registrant of a facility shall ensure that a physician assistant delegated the performance of specified fluoroscopic procedures by a supervising physician has submitted documentation of the following to the facility:

120.405: continued

(a) Successful completion of the education and clinical training specified in 105 CMR 120.405(K)(3) offered by an approved provider;

(b) a passing score on an examination offered by the American Registry of Radiologic Technologists (ARRT) or equivalent exam approved by the Agency covering the educational and clinical requirements specified in 105 CMR 120.405(K)(3);

(c) a written and signed statement from the physician assistant's supervising physician, who meets the requirements of 105 CMR 120.405(K)(1)(a) or (b), verifying the physician assistant's competency to perform specified fluoroscopic procedures; and

(d) a written practice agreement between the physician assistant and his or her supervising physician as set forth in regulations of the Board of Registration in Medicine at 243 CMR 2.08 and of the Board of Registration of Physician Assistants in 263 CMR 5.00: *Scope of Practice and Employment of Physician Assistants*.

(3) The education and clinical training required by 105 CMR 120.405(K)(2)(a) shall consist of the following:

(a) Didactic Content

1. Digital image acquisition and display;
2. Contrast media;
3. Fluoroscopic unit operation and safety;
4. Image analysis;
5. Radiation biology;
6. Radiation production and characteristics; and
7. Radiation protection.

(b) Clinical Component

1. Clinical competency requirement: 40 clinical hours performing fluoroscopic procedures in a fluoroscopic suite under the direct supervision of a physician who meets the requirements of 105 CMR 120.405(K)(1)(a) or (b), a medical physicist, or a radiography educator. "Direct supervision," as used in 105 CMR 120.405(K)(3), means physically present where the fluoroscopic procedure is being performed and immediately available and able to provide assistance and direction throughout the procedure;

2. Fluoroscopic device orientation: safe and proper manipulation of the fluoroscopic device.

(4) The Registrant of the facility and/or responsible person at the facility shall maintain all records relating to compliance with the education and clinical training requirements for the current year and the previous four years.

(5) The facility shall establish policies and procedures for limiting the performance of fluoroscopic procedures to only those health care providers who have met the requirements of 105 CMR 120.405(K) and who have been granted privileges for the use of fluoroscopy based on their demonstrated competency in the performance of fluoroscopic procedures.

(6) The Registrant of the facility shall ensure that all physicians who are not board certified in radiology and who perform fluoroscopic procedures complete two hours of training in Radiation Safety/Radiation Protection on an annual basis, and that all physicians who are not board certified in radiology who supervise the performance of fluoroscopic procedures complete a total of four hours of Radiation Safety/Radiation Protection training on an annual basis. The facility shall maintain all records relating to compliance with this training requirement for the current year and the previous four years.

(7) The Registrant of a facility shall ensure that licensed radiologic technologists and licensed physician assistants who perform fluoroscopic procedures have satisfied all related continuing education requirements as required by their respective licensing boards, and shall maintain records documenting completion of such continuing education requirements by radiologic technologists and physician assistants for five years.

(8) In addition to any other reporting requirements, the facility shall immediately, and no later than 24 hours after discovery, report to the Agency any incident at the facility involving fluoroscopic procedures that seriously affects the health and safety of a patient or that causes serious physical injury to a patient due to radiation exposure.

120.405: continued

(9) Nothing in 105 CMR 120.405(K) shall prohibit nurse practitioners from practicing within their lawful scope of practice, including functioning as first assistants during cardiac catheterization procedures in accordance with 105 CMR 130.900: *Standards for Operation of Hospital-based Cardiac Catheterization Services*, and the Board of Registration in Nursing Advisory Ruling Number 0201, *Nurse Practitioner as First Assistant in Cardiac Catherization*, provided that the physician who is the primary operator, as defined in 105 CMR 130.910, is qualified to operate fluoroscopic x-ray systems pursuant to 105 CMR 120.405(K)(1)(a) or (b).

(L) Patient Dose Evaluation.

(1) Each facility performing fluoroscopically-guided interventional and CT fluoro procedures shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury as further defined in 105 CMR 120.405(L)(5).

(2) Records documenting that policies and procedures have been developed to determine that those procedures that have a potential to result in patient doses exceeding the threshold for injury have been established to reduce the probability of such exposures and that appropriate action occurs for patients receiving doses that warrant follow-up.

(3) The facility shall have a patient dose monitoring procedures in place. When the fluoroscopy unit is equipped with an Air-Kerma dose readout, the recording of this value shall suffice as a patient dose record.

(4) The facility shall document in the patient's medical record an estimate of the absorbed dose to the skin.

(5) Any cumulative absorbed dose to the skin equal to or greater than 2 Gy (200 rads) shall be noted in the patient's medical record and reviewed by the Radiation Safety Committee.

(6) Each facility that use fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name. The record shall be maintained for five years.

(M) Equipment Operation.

(1) Radiological technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or a licensed Radiological Technologist.

(2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(N) Mini-C-Arms. 105 CMR 120.405 includes Mini-C-Arms.

120.406: Diagnostic X-ray Systems

(A) Beam Limitation Except for Mammographic Systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 105 CMR 120.406(G)(2) has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

(1) General Purpose Stationary and Mobile X-ray Systems, Including Veterinary Systems (Other than Portable) Installed After December 31, 1997.

(a) Only x-ray systems provided with a means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used;

(b) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam;

(c) The Agency may grant an exemption on non-certified x-ray systems to 105 CMR 120.406(A)(1)(a); and,

(d) Provided the registrant makes a written application for such exemption and in that application:

120.406: continued

1. Demonstrates it is impractical to comply with 105 CMR 120.406(A)(1)(a) and (b); and,

2. The purpose of 105 CMR 120.406(A)(1)(a) and (b) will be met by other methods.

(2) Additional Requirements for Stationary General Purpose X-ray Systems. In addition to the requirements of 105 CMR 120.406, all stationary general purpose x-ray systems, both certified and non-certified shall meet the following requirements:

(a) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within 2%;

(b) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and,

(c) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Radiographic Systems Other Than Those Designated in 105 CMR 120.406(A)(1) through (3).

(a) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

(c) 105 CMR 120.406(A)(4)(a) and (b) may be met with a system that meets the requirements for a general purpose x-ray system as specified in 105 CMR 120.406(A)(1) or, when alignment means are also provided, may be met with either:

1. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or,

2. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(B) Radiation Exposure Control.

(1) Timers. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

120.406: continued

(3) Exposure Termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(a) Manual Exposure Control.

An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

1. Exposure of ½ second or less; or,
2. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(b) Automatic Exposure Controls. When an automatic Exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;
2. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
3. The minimum exposure time for all equipment other than that specified in 105 CMR 120.406(B)(3)(b)2. shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;
4. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and,
5. A visible signal shall indicate when an exposure has been terminated at the limits required by 105 CMR 120.406(B)(3)(b)4., and manual resetting shall be required before further automatically timed exposures can be made.

(4) Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios ($X_i$) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$

where $X_1$ and $X_2$ are the average C $kg^{-1}s^{-1}$ (mR/s) values.

(5) Exposure Control Location. The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

(6) Operator Protection, Except Veterinary Systems.

(a) Stationary Systems. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

(b) Mobile and Portable Systems. Mobile and portable x-ray systems which are:

1. Used continuously for greater than one week in the same location, *i.e.*, a room or suite, shall meet the requirements of 105 CMR 120.406(B)(6)(a);
2. Used for less than one week at the same location shall be provided with either a protective barrier at least 6.5 feet (two m) high for operator protection during exposure, or means shall be provided to allow the operator to be at least nine feet (2.7 m) from the tube housing assembly during the exposure.
3. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(7) Exposure Reproducibility. When all techniques factors are held constant, including control panel selections associated with exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

120.406: continued

(C) Source-to-skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

(D) Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgen (0.516 μC/kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(E) Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value for kVp and 20% for time.

(F) mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated:

(1) Equipment Having Independent Selection of X-ray Tube Current (mA). The average ratios ($X_i$) of air kerma to the indicated milliampere-seconds product (C $kg^{-1}$ $mAs^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where $X_1$ and $X_2$ are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

(2) Equipment Having a Combined X-ray Tube Current-exposure Time Product (mAs) Selector. The average ratios ($X_i$) of air kerma to the indicated milliampere-seconds product, in units of C $kg^{-1}$ $mAs^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where $X_1$ and $X_2$ are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

(3) Measuring Compliance. Determination of compliance shall be based on three exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(G) Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Beam Limitation for Portable X-ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 105 CMR 120.406(A)(1).

(2) Field Limitation and Alignment on Stationary General Purpose X-ray Systems. For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(C):

120.406: continued

(a) Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five seconds or is manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.

(b) The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than 2% of the SID and that the sum of the length and width differences without regard to sign be no greater than 3% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

(c) The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than five by five centimeters. Return to positive beam limitation as specified in 105 CMR 120.406(F)(6)(a) and (b) shall occur upon a change in image receptor.

(d) Positive beam limitation may be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or when either the beam axis or table angulation is not within 10° of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.

(e) A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode It shall be impossible to remove the key while the positive mode is overridden.

(3) Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(4) Transmission Limit for Image Receptor Supporting Devices Used for Mammography. For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the Exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 C/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(H) Any facility that utilizes a CR or DR system shall follow the manufacturer's recommendations for Quality Assurance and Quality Control.

(1) All Quality Control tests and results shall be documented.

(2) Quality assurance and quality control records shall be maintained for a minimum of 24 months and readily available for review by representatives of the Department.

120.407: Dental Radiographic Systems

(A) General Requirements.

(1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Reproducibility. With a timer setting of 0.3 second or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period ($T_{max}$) minus the minimum exposure period ($T_{min}$) when 4 timer tests are performed:

$$T \geq 5(T_{max} - T_{min})$$

120.407: continued

(3) X-ray Control.

(a) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

(b) The exposure switch shall be of the dead-man type.

(c) Each x-ray control shall be located in such a way as to permit the operator to remain in an area of less than two millirems in any one hour during the entire exposure.

(4) Exposure Reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four Exposures are made at identical technique factors, the value of the average Exposure (E) is greater than or equal to five times the maximum Exposure ($E_{max}$) minus the minimum Exposure ($E_{min}$):

$$E \geq 5(E_{max} - E_{min})$$

(B) Additional Requirements for Dental Intraoral Systems.

(1) Source-to-skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD to not less than:

(a) 18 centimeters if operable above 50 kVp; or,

(b) ten centimeters if not operable above 50 kVp.

(2) Field Limitation.

(a) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the x-ray field, at the minimum SSD. shall be containable in a circle having a diameter of no more than seven centimeters.

(b) An open-ended beam-indicating device shall be used.

(C) Additional Requirements for Dental Extraoral System Field Limitation.

(1) Dental rotational panoramic systems shall be provided with means to limit the x-ray beam to the imaging slit in the transverse axis and shall not exceed a total of 0.5 inch larger than the imaging slit in the vertical axis.

(2) All other dental extraoral radiographic systems (*e.g.*, cephalometric) shall be provided with means to both size and align the x-ray field so that it does not exceed beyond any edge of the image receptor by more than 2% of the SID.

(D) Additional Requirements Applicable to Certified Systems Only. Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation Exposure shall be no greater than 0.05, for any specific combination of selected technique factors.

(2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100% of the maximum rating, the average ratios of Exposure to the indicated milliampere-seconds product obtained at any 2% consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1\text{-}X_2 \leq 0.10\,(X_1 + X_2)$$

where: $X_1$ and $X_2$ are the average mR/mAs values obtained at each of two consecutive tube current settings.

(3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

120.407: continued

(5) Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of 105 CMR 120.404(E)(1).

(E) Additional Operation Controls for Dental Radiographic Systems.

(1) Film holding devices shall be used except in individual cases in which the practitioner has determined that such holding are contraindicated. Written safety procedures required by 105 CMR 120.400 shall state the criteria under which the exception shall apply.

(2) The tube housing support shall be constructed and adjusted so that the tube housing shall not drift from its set position during an exposure. Neither the tube housing nor the support housing shall be hand-held during an exposure.

(3) The operator shall stand at least six feet from the useful beam or behind a protective barrier. Where a protective barrier is utilized, a viewing system shall be used.

(4) Individuals who operate only dental radiographic systems are exempt from the personnel monitoring requirements of 105 CMR 120.211.

(5) Protective equipment -aprons and shields-shall be checked annually for defects, such as holes, cracks, and tears to assure reliability and integrity and documentation shall be kept for five years.

(6) Thyroid shields shall be used on all patients, when applicable.

(7) The registrant of the facility shall ensure that the equipment is in safe operating condition:

(a) when it is first installed and prior to use on patients;

(b) after any major changes or replacement of parts and prior to use on patients:

(c) by having calibrations and preventative maintenance:

1. such preventative maintenance or calibrations shall not exceed three years

2. the preventative maintenance or calibrations shall be performed by a registered service provider as specified in 105 CMR 120.026.

(d) Preventative maintenance and calibrations shall be reviewed and signed within a reasonable time of completion of the tests but no longer than 30 days of completion of the tests by the licensed dentist, and any necessary corrective action shall be implemented within 30 days.

(e) Records of the last two calibrations and preventative maintenance shall be maintained at the facility.

(F) Hand-held Intraoral Dental Radiographic Units.

(1) For all uses:

(a) Operators of hand-held intraoral dental radiographic units shall be specifically trained to operate such equipment.

(b) When operating a hand-held intraoral dental radiographic unit, operators shall wear a lead apron and thyroid collar, unless otherwise authorized by the Agency or a qualified health or medical physicist.

(c) A hand-held intraoral dental radiographic unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.

(d) Unless otherwise authorized by the Agency, a hand-held intraoral dental radiographic unit shall be used with a secondary radiation block.

(e) The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held intraoral radiographic unit.

(2) Additional requirements for operatories in permanent facilities:

(a) Hand-held intraoral dental radiographic units shall be used for patient examinations in dental operatories that meet the structural shielding requirements specified by the Agency or by a qualified health or medical physicist.

(b) Hand-held intraoral dental radiographic units shall not be used for patient examinations in hallways and waiting rooms.

(G) Cone Beam 3-D Dental Imaging Systems.

(1) Facilities shall maintain documentation of applications from the manufacturer;

(2) Operators of the unit shall be a:

120.407: continued

(a) Licensed Dentist or
(b) Licensed Hygienist or Certified Dental Assistant

(3) All facilities that use a Cone Beam CT unit shall follow the manufacturer's recommendations for Quality Control;

(4) All facilities shall perform calibrations and preventative maintenance annually.

(5) Preventative maintenance, surveys, and calibrations shall be reviewed and signed within a reasonable time of completion of the tests but no longer than 30 days of completion of the tests by a qualified medical physicist and the licensed dentist and any necessary corrective action shall be implemented within 30 days.

120.408: Veterinary X-ray Systems

(A) Equipment.

(1) Technique and Exposure Indicators.

(a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(b) The requirements of 105 CMR 120.408(A)(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(c) The x-ray control shall provide visual indication of the production of x-rays observable at or from the operator's protected position whenever x-rays are produced.

(2) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgen in one hour when the x-ray tube is operated at its leakage technique factors. Measurement is averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(3) The useful beam shall be restricted to the area of clinical interest and no larger than the size of the image receptor.

(4) Collimating devices shall be provided and shall limit the beam to the area of the image receptor to within 2% of the SID, and shall provide the same degree of protection as is required of the housing.

(5) The half-value layer of the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters and 70 kVp, and two millimeters aluminum equivalent for machines operating above 70 kVp.

(6) A device shall be provided to terminate the exposure after a preset time or Exposure.

(7) A dead-man type of exposure switch shall be provided, together with an exposure cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures.

(8) The coefficient of variation of Exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four Exposures are made at identical technique factors, the value of the average Exposure (E) is greater than or equal to five times the maximum Exposure ($E_{max}$) minus the minimum Exposure ($E_{min}$):

$$E \geq 5 (E_{max} - E_{min})$$

(9) The primary beam shall be aligned with the film by using specified techniques in the facility's operating procedures.

(10) Fluoroscopic, CT, and therapy systems used in veterinary facilities shall meet the requirements of 105 CMR 120.405, 120.409 and 120.410 respectively, except the aural communications of 105 CMR 120.400, 120.422: *Appendix C*, 120.409(B)(1) and 120.410(B)(1).

(11) Portable machines shall be used in a manner which complies with 105 CMR 120.000.

(B) Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 105 CMR 120.211, 120.221 and 120.222.

120.408: continued

(C) Additional Operational Controls for Veterinary Facilities.

(1) All exams and retakes shall be ordered by the veterinarian.

(2) The x-ray tube shall not be held by any individual during radiographic exposures.

(3) Unless required to restrain an animal, the operator shall stand at least six feet away from the useful beam and the animal during radiographic exposures.

(4) No individual, other than the operator, shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required.

(5) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be used when technique permits.

(6) A pregnant female shall not hold or restrain an animal.

120.409: Computed Tomography (CT) X-ray Systems

Any facility offering CT services after April 30, 2011 shall have ACR accreditation.

Definitions. In addition to the definitions provided in 105 CMR 120.402, the following definitions shall be applicable

Computed Tomography Dose Index (CTDI) means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{n\,T}\int_{-7T}^{+7T} D(z)\,dz$$

where:

z = Position along a line perpendicular to the tomographic plane;

D(z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

Computed Tomography Dose Index (CTDI) assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

CT Dosimetry Phantom means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

Dose Profile means the dose as a function of position along a line.

Modulation Transfer Function means the modulus of the Fourier transform of the impulse response of the system.

120.409: continued

Noise means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (Sn) is calculated using the following expression:

$$S_n = \frac{100 \bullet \overline{CS} \bullet s}{\mu_w}$$

where:

$\overline{CS}$ = Linear attenuation coefficient of the material of interest.

$\mu_w$ = Linear attenuation coefficient of water.

$s$ = Standard deviation of the CTN of picture elements in a specified area of the CT image.

Picture Element means an elemental area of a tomogram.

Remanufacturing means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT x-ray system manufactured by the original manufacturer on or after November 29, 1984. Any reference in 105 CMR 120.408 to manufacture, manufacturer, or manufacturing includes remanufacture, remanufacturing, respectively.

Sensitivity Profile means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

Single Tomogram System means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

(A) Equipment Requirements.

(1) Tomographic Plane Indication and Alignment.

(a) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(b) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

(c) If a device using a light source is used to satisfy 105 CMR 120.409(A)(1)(a) or (b), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux

(2) Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(3) Initiation of Operation.

(a) The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(b) Means shall be provided to require operator initiation of each individual scan or series of scans.

(c) All emergency buttons/switches shall be clearly labeled as to their functions.

(4) Termination of Exposure.

(a) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices which monitor equipment function.

120.409: continued

(b) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 105 CMR 120.409(A)(4)(a).

(c) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than 0.5 second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.

(5) Extraneous Radiation. The system shall perform such that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time that scans are not being performed does not exceed the levels permitted by 105 CMR 120.404(C).

(6) Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured after September 3, 1985.

(a) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.

(b) If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 seconds. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(c) The deviation of indicated scan increment versus actual increment shall not exceed to within one millimeter with any mass from zero to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

(B) Facility Design Requirements.

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

(2) Viewing System.

(a) Windows, mirrors, closed-circuit television, or an equivalent shall be provided 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.

(b) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

(C) Dose Measurements, Spot Checks, Surveys, and Calibrations.

(1) Dose Measurements.

(a) Dose measurements of the radiation output of the CT x-ray system shall be performed by a qualified medical physicist.

(b) Dose measurements of a CT x-ray system shall be performed at intervals specified by a qualified medical physicist and after any change or replacement of components which, in the opinion of a qualified medical physicist, could cause a change in the radiation output.

(c) Measurements of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated or inter compared with a calibrated chamber within the preceding two years. The calibration of such system shall be traceable to a national standard.

(d) Calibration procedures shall be in writing. Records of calibration performed shall be maintained for inspection by the Radiation Control Program.

(2) Spot Checks.

(a) Spot check procedures shall be in writing and developed by a qualified medical physicist.

(b) All spot checks shall be included in the calibration required by 105 CMR 120.409(C)(1), and otherwise at time intervals and system conditions specified by a qualified medical physicist.

(c) Spot checks shall include acquisition of images obtained with the phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by 105 CMR 120.409(C)(1). The images shall be retained until a new dose measurement is performed in two forms as follow:

120.409: continued

1. Photographic copies of the images obtained from the image display device; and
2. Images stored in digital form of the most recent spot check on a storage medium compatible with the CT x-ray system.

(d) The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

(e) Written records of the spot checks performed shall be maintained for inspection by the Agency.

(3) Surveys .

(a) All CT x-ray systems installed after March 3, 2012 and those systems not previously surveyed shall have a survey made by a qualified medical physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(b) The registrant of the facility [licensee] shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the Agency upon request.

(4) Physics Evaluations.

(a) The physics evaluation of the radiation output of the CT x-ray system shall be performed by a qualified medical physicist.

(b) The physics evaluation of a CT x-ray system shall be performed after initial installation and before use on human patients, annually or at intervals specified by a qualified medical physicist, and after any change or replacement of components which, in the opinion of the qualified medical physicist, could cause a change in the radiation output.

(c) The physics evaluation of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The physics evaluation of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

(d) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

1. CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;
2. CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;
3. Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;
4. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(e) The physics evaluation shall be required for each type of head, body, or whole-body scan performed at the facility.

(f) Physics evaluation shall meet the following requirements:

1. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

120.409: continued

2. The CTDi[2] along the two axes specified in 105 CMR 120.409(C)(4)(d)2. shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

3. The spot checks specified in 105 CMR 120.409(C)(2) shall be made.

(D) Additional Operational Controls for CT X-Ray Systems.

(1) The CT x-ray system shall only be operated by an individual who has been specifically trained in its operation and who holds a valid Massachusetts license in radiologic technology.

(2) Information shall be available at the control panel or in a specified location regarding the operation and calibration of the system. The information shall contain:

(a) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(b) The results of at least the most recent checks conducted on the system; and,

(c) The distance, in millimeters, between the tomographic plane and the reference plane, if a reference plane is utilized.

(3) If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified medical physicist.

(4) Quarterly reviews shall be conducted of dose protocols being used at the facility.

(5) Dose indicators shall be included in the patient's medical record.

(E) Mini CT Units.

(1) All facilities that use a Mini CT unit shall follow the manufacturer's recommendations for Quality Control.

(2) Operators of Mini CT units shall be:

(a) Licensed physician; or

(b) Licensed as a Radiologic Technologist.

(3) Each facility shall maintain the records of applications from the manufacturer.

120.410: Bone Densitometry

(A) Bone Densitometry Systems shall be:

(1) Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C – Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act.;

(2) Registered in accordance with 105 CMR 120.020;

(3) Maintained and operated in accordance with the manufacturer's specifications.

(B) Equipment Requirements. Systems with stepless collimators shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2% of the SID.

(C) Operators of Bone Densitometry Systems shall be:

(1) Licensed as a radiologic technologist [by the Agency]; or

(2) A licensed physician; or

(3) International Society For Clinical Densitometry certified as a bone densitometry technologist; or

(4) ARRT certified in Bone Density

[2] For the purpose of determining the CTDI, the manufacturer's statment as to the nominal tomographic section thickness for that particular system may be utilized.

120.410: continued

(D) During the Operation of any Bone Densitometry System:
(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.
(2) The operator shall advise the patient that the bone densitometry examination is a type of x-ray procedure.

(E) The Manufacturer's Quality Assurance and Quality Control programs shall be followed.

(F) The registrant of the facility shall keep maintenance records for bone densitometry systems. These records shall be maintained for inspection by the Agency for three years.

(G) Bone Densitometry on Human Patients Shall be Conducted Only:
(1) Under a prescription of a licensed practitioner of the healing arts; or
(2) Under a screening program approved by the Agency.

(H) Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in 105 CMR 120.421: *Appendix B* and include the name and address of the individual who will interpret the screening results.

(I) 105 CMR 120.010 includes CT units that are designed for bone density.

120.420: Appendix A -- Radiation Shielding and Safety Requirements

In order for the Radiation Control Program to provide an evaluation, and official approval on shielding requirements for a radiation installation, the following must be submitted. The plans shall show as a minimum the following:

(A) The normal location of the x-ray system's radiation port, the port's travel and transverse limits, general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth and the location of the x-ray control panel.

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

(C) The dimensions of the room(s) concerned.

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

(E) The make and model of the x-ray equipment.

(F) The typical type of examination(s) and treatment(s) which will be performed with the equipment.

(G) Information on the anticipated workload of the x-ray system(s).

(H) An interlock and/or warning light shall be installed at all egresses. For diagnostic x-ray installations, the warning light shall be wired to the rotor of the x-ray system.

(I) All basic assumptions used to determine the shielding requirements in developing these plans shall be submitted with these plans.

120.421: Appendix B -- Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

120.421: continued

(A) Name and address of the applicant and, where applicable, the names and addresses of agents within this Commonwealth.

(B) Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

(C) A detailed description of the x-ray examinations proposed in the screening program.

(D) Description of the population to be examined in the screening program, *i.e.*, age, sex, physical condition, and other appropriate information.

(E) An evaluation of any known alternate methods not involving ionizing radiation, which would achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.

(F) An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of 105 CMR 120.000.

(G) A description of the diagnostic film quality control program.

(H) A copy of the technique charts for the x-ray examination procedures to be used.

(I) The qualifications of each individual who will be operating the x-ray system(s).

(J) The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

(K) The name and address of the individual who will interpret the radiograph(s).

(L) Procedures to be used in advising the individuals screened and their practitioner of the healing arts or healthcare provider of the results of the screening procedure and any further medical needs indicated.

(M) The duration of the screening program.

120.422: Appendix C -- Design Requirements for an Operator's Booth

(A) Space Requirements

(1) The operator shall be allotted not less than 7.5 square feet (0.697 $m^2$) of unobstructed floor space in the booth.

(2) The operator's booth may be any geometric configuration with no dimension of less than two feet (0.61 m).

(3) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables or other similar encroachments.

(4) The booth shall be located or constructed such that unattenuated direct scatter radiation originating in the examination table or at the wall cassette shall not reach the operator's station in the booth.

(B) Structural Requirements

(1) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high.

(2) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(3) Shielding shall be provided to maintain exposure inside the booth equal to or less than two mR per week.

(C) X-ray Control Placement. The x-ray exposure switch for the system shall be fixed within the booth and;

(1) Shall be at least 40 inches (1.02 m) from any open edge of the booth and;

(2) Shall allow the operator to use the majority of the available viewing windows.

120.422: continued

(D) Viewing System Requirements.

(1) Each booth shall have at least one viewing device which will:

(a) Be so placed that the operator can view the patient during any exposure; and,

(b) The device should be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure, which will prevent the exposure if the door is not closed.

(2) When the viewing system is a window, the following requirements also apply:

(a) The viewing area shall be at least one square foot (0.0929 $m^2$).

(b) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457m) from the edge of the booth.

(c) The material constituting the window shall have at least the same lead equivalence as that required in the booth's walls in which it is mounted.

(3) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 105 CMR 120.422: *Appendix C*(A)(4).

(4) When the viewing system is by electronic means:

(a) The camera shall be so located as to accomplish the general requirements of 105 CMR 120.421: *Appendix C*(A)(4); and,

(b) There shall be an alternate viewing system as a backup for the primary system.

(c) Means shall be provided for the operator to be able to orally communicate with the patient at all times.

NON-TEXT PAGE

120.423: Appendix D – Exemptions from Shielding for Certain Fluoroscopic Procedures

(A) Angiograms

(B) Arthrograms

(C) Biliary drainage procedures

(D) Fluoroscopic biopsy procedures

(E) Myelograms

(F) Percutaneous cholangiograms

(G) Percutaneous nephrostomies

(H) Sinograms or fistulograms

(I) T-tube cholangiograms

120.430: THERAPEUTIC RADIATION MACHINES IN THE HEALING ARTS

120.431: Purpose and Scope

(A) 105 CMR 120.430 establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of 105 CMR 120.430 are in addition to, and not in substitution for, other applicable provisions of 105 CMR 120.000.

(B) 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 105 CMR 120.433(C).

120.432: Definitions

As used in 105 CMR 120.430, the following definitions apply:

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

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

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

120.432: continued

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

Barrier (*See* Protective Barrier in 105 CMR 120.005).

Beam Axis means the axis of rotation of the beam limiting device.

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

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

Beam Scattering Foil means a thin piece of material (usually metallic) placed in the beam to 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.

Certified Health Physicist means and individual certified by the American Board of Health Physics as a health physicist.

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 target to skin distance (TSD), usually less than five centimeters.

Conventional Simulator means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

Detector (*See* Radiation Detector in 105 CMR 120.402).

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

Dosimetry System means a device which can measure radiation dose.

Electronic Brachytherapy means a method of radiation therapy using an electrically generated source of ionizing radiation to deliver a radiation dose at a distance of up to a few centimeters by intracavitary, intraluminal or interstitial application, or by applications with the source in contact with the body surface or very close to the body surface.

Electronic Brachytherapy Device means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

Electronic Brachytherapy Source means the x-ray tube component used in an electronic brachytherapy device.

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 flatten the absorbed dose rate over the radiation field.

120.432: continued

Filter means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 105 CMR 120.436.

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

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

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

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.

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

Leakage Radiation means radiation emanating from the radiation therapy system except for the useful beam.

Light Field means the area illuminated by light, 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.]

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

Monitor Unit (MU) (*See* Dose Monitor Unit).

Moving Beam Radiation Therapy means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation 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.

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.

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

420.432: continued

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

Primary Protective Barrier (*See* 105 CMR 120.005: Protective Barrier).

Qualified Medical Physicist means an individual qualified in accordance with 105 CMR 120.433(D).

Radiation Field (*See* Useful Beam)

Radiation Head means the structure from which the useful beam emerges.

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

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 in 105 CMR 120.005).

Simulator (Radiation Therapy Simulation System) means any x ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. (*See*: Conventional Simulator and Virtual Simulator.)

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

Source-skin Distance (SSD) (*See* Target-skin Distance).

Stationary Beam Radiation Therapy means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

Stray Radiation means the sum of leakage and scattered radiation.

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

Target-skin Distance (TSD) means the distance measured along the beam axis from the target to the surface of the irradiated object or patient.

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

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. For the purpose of 105 CMR 120.000, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

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.

120.432: continued

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

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 useful beam.

Written Directive means an order, such as a physician's prescription, in writing, by an authorized user for the administration of radiation to a specific patient or human research subject, as specified in 105 CMR 120.435(A).

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

120.433: General Administrative Requirements for Facilities Using Therapeutic Radiation Machines

(A) 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 105 CMR 120.430 are met in the operation of the therapeutic radiation machine(s).

(B) Prohibition A therapeutic radiation machine which does not meet the provisions of 105 CMR 120.000 shall not be used for irradiation of patients.

(C) Training for Therapeutic Radiation Machine Authorized Users The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall require the authorized user to be a physician who:

(1) Is certified in:

(a) Radiology or therapeutic radiology by the American Board of Radiology; or

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

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

(d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.

(2) 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 three years of supervised clinical experience.

(a) To satisfy the requirement for instruction in 105 CMR 120.433(C)(2), the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of ionization radiation; and
4. Radiation biology.

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

1. Review of the full calibration measurements and periodic quality assurance checks;
2. Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
3. Using administrative controls to prevent misadministrations;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of a external beam radiation therapy unit or console; and,
5. Checking and using radiation survey meters.

120.433: continued

(c) To satisfy the requirement for a period of supervised clinical experience, training shall include one 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 year years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/ contraindications;
2. Selecting proper dose and how it is to be administered;
3. Calculating thetherapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and,
4. Post administration follow up and review of case histories.

(d) Notwithstanding the requirements of 105 CMR 120.433(C)(1) and (2), the registrant for any therapeutic radiation machine subject to 105 CMR 120.436 may also submit the training of the prospective authorized user physician for Agency review on a case by case basis.

(e) 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.

(D) Training for Qualified Medical Physicist for Radiation Therapy. The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall require the Qualified Medical Physicist to:

(1) Be registered with the Agency, under the provisions of 105 CMR 120.026, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and,

(2) Be certified by the American Board of Radiology in:

(a) Therapeutic radiological physics; or
(b) Roentgen-ray and gamma-ray physics; or
(c) X-ray and radium physics; or
(d) Radiological physics; or,

(3) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or,

(4) Be certified by the Canadian College of Medical Physics.

(E) Qualifications of Operators.

(1) Individuals who will be operating a therapeutic radiation machine for medical use shall possess a valid Massachusetts License as a Radiologic Technologists in Radiation Therapy.

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

(F) Written safety procedures and rules shall be developed by a Qualified Medical Physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

(G) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by an authorized user meeting the requirements of 105 CMR 120.433(C) who is specifically identified on the Certificate of Registration. 105 CMR 120.433(G) specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

120.433: continued

(H) Visiting Authorized User. Notwithstanding the provisions of 105 CMR 120.433(G), a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

(1) The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee; and

(2) The visiting authorized user meets the requirements established for authorized user(s) in 105 CMR 120.433(C)(1) and (2); and

(3) The registrant maintains copies of all records specified by 105 CMR 120.433(H) for five years from the date of the last visit.

(I) 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 written directive program. In addition to the requirements of 105 CMR 120.430, these individuals are also subject to the requirements of 105 CMR 120.201 and 120.205.

(J) 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) Report of acceptance testing;

(2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 105 CMR 120.430, as well as the name(s) of person(s) who performed such activities;

(3) Records of maintenance and/or modifications performed on the therapeutic radiation machine after July 9, 1999, as well as the name(s) of person(s) who performed such services;

(4) Signature of the Radiation therapy Physicist or Authorized User authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(K) Records Retention. All records required by 105 CMR 120.430 shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in 105 CMR 120.430. 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.

120.434 General Technical Requirements for Facilities Using Therapeutic Radiation Machines

(A) Protection Surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated in accordance with 105 CMR 120.438. The radiation protection survey shall be performed by, or under the direction of, a Qualified Medical Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation. The following standards must be met and recorded:

(a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 105 CMR 120.211(A); and,

(b) Radiation levels in unrestricted areas do not exceed the limits specified in 105 CMR 120.221(A) and (B).

(2) In addition to the requirements of 105 CMR 120.434(A)(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

(a) After making any structural or composite modifications to the treatment room shielding;

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

(c) After relocating the therapeutic radiation machine; or

120.434: continued

(d) 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.

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

(4) If the results of the surveys required by 105 CMR 120.434(A)(1) or (2) indicate any radiation levels in excess of the respective limit specified in 105 CMR 120.434(A)(1), the registrant shall lock the control in the "OFF" position and not use the unit:

(a) 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

(b) Until the registrant has received a specific exemption from the Agency.

(B) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by 105 CMR 120.434(A) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 105 CMR 120.221(A) and (B), before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 105 CMR 120.221(A) and (B);

(2) Perform the survey required by 105 CMR 120.434(A) again; and,

(3) Include in the report required by 105 CMR 120.434(D) the results of the initial survey, a description of the modification made to comply with 105 CMR 120.434(B)(1), and the results of the second survey; or,

(4) Request and receive a registration amendment under 105 CMR 120.221(C). that authorizes radiation levels in unrestricted areas greater than those permitted by 105 CMR 120.221(A) and (B).

(C) Dosimetry Equipment.

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

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

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

(2) 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 105 CMR 120.434(C)(1) This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 105 CMR 120.434(C)(1);

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 105 CMR 120.434(C)(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Qualified Medical Physicist.

120.434: continued

(D) Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall furnish a copy of the records required in 105 CMR 120.434(A) and (B) to the Agency within 30 days following completion of the action that initiated the record requirement.

120.435: Written Directives

(A) A written directive, as defined in 105 CMR 120.432, must be dated and signed by an authorized user prior to the administration of radiation.

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 will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment target volume, and number of fractions.

(C)(1) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

If because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The registrant shall retain a copy of the written directive for three years.

(D) Procedures for Administrations of Doses of Radiation. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

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

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

(3) Therapeutic radiation machine approved isodose plan and related calculations are in accordance with the respective written directives by:

(a) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive approved by the authorized user and reviewed by the qualified medical physicist; and

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

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

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

(E) Reports and Notification of Medical Events.

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

(a) A dose that differs from the prescribed dose by more than 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

1. The total dose delivered differs from the prescribed dose by 20% or more;

2. The calculated weekly administered dose differs from the weekly prescribed dose by 30% or more; or

3. For a planned treatment course of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose; or

120.435: continued

4. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

(b) A dose that exceeds 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

1. An administration of a dose or dosage to the wrong individual or human research subject; or
2. An administration of a dose delivered by the wrong mode of treatment;

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% of the dose expected from the administration defined in the written directive.

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

(3) The registrant shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The registrant shall submit a written report to the Agency within 15 days after discovery of the medical event.

(a) The written report must include:

1. The registrant's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the individual(s) who received the administration;
6. Actions, if any, that have been taken, or are planned, to prevent recurrence;
7. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The registrant shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

(6) Aside from the notification requirement, nothing in 105 CMR 120.435 affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall retain a record of a medical event in accordance with 105 CMR 120.435(E). A copy of the record required under 105 CMR 120.435(E) shall be provided to the referring physician if other than the registrant, within 15 days after discovery of the medical event.

(F) Records of Medical Events. A registrant shall retain a record of medical events reported in accordance with 105 CMR 120.435(E) for three years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event; medical event a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

120.436: Therapeutic Radiation Machines of Less than 500 kV

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

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

(2) >50 and <500 kV Systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one cGy (one rad) 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 five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

(3) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 105 CMR 120.436(A)(1) and (2) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

(B) 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.

(C) Adjustable or Removable Beam Limiting Devices.

(1) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than 5% of the useful beam for the most penetrating beam used;

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

(D) Filter System. The filter system shall be so designed that:

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

(2) For equipment installed after July 9, 1999, an interlock system prevents irradiation if the proper filter is not in place;

(3) The air kerma rate at a distance of one meter from the filter shall not exceed one cGy (one rad) per hour under any operating conditions; and,

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

(E) Tube Immobilization.

(1) The x-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and

(2) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

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

(G) 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.

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

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

(2) 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;

(3) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(4) The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

120.436: continued

(5) The timer shall not permit an exposure if set at zero;
(6) 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,
(7) The timer and back-up timer if present shall be accurate to within 1% of the selected value or one second, whichever is greater.

(I) Control Panel Functions. The control panel, in addition to the displays required by other provisions in 105 CMR 120.436, shall have:
(1) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
(2) An indication of whether x-rays are being produced;
(3) Means for indicating x-ray tube potential and current;
(4) The means for terminating an exposure at any time;
(5) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
(6) For therapeutic radiation machines manufactured after July 9, 1999, a positive display of specific filter(s) in the beam.

(J) Multiple Tubes. When a control panel is capable of energizing more than one x-ray tube:
(1) It shall only be allowable to activate one X-ray tube at any time;
(2) There shall be an indication at the control panel identifying which x-ray tube is activated; and
(3) There shall be an indication at the tube housing assembly when that tube is energized.

(K) Target-to-skin Distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

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

(M) 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.

(N) 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 of 105 CMR 120.439, the treatment room shall meet the following design requirements:
(1) Aural Communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;
(2) Viewing Systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system 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.

(O) Additional Requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:
(1) All protective barriers shall be fixed except for entrance doors or beam interceptors;
(2) The control panel shall be located outside the treatment room or inside the treatment room within a totally enclosed booth with protective barrier walls, door(s), ceiling and floor;
(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

140.436: continued

(4) When any door referred to in 105 CMR 120.436(O)(3) is opened while the x-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

(P) Full Calibration Measurements.

(1) Full calibration of a therapeutic radiation machine subject to 105 CMR 120.436 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist:

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

(b) At intervals not exceeding one year; and

(c) Before medical use under the following conditions:

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

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

(d) Notwithstanding the requirements of 105 CMR 120.436(P)(1)(c):

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

2. If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 105 CMR 120.436(P)(1)(c)1.

(2) To satisfy the requirement of 105 CMR 120.436(P)(1), 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).

(3) 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 both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Qualified Medical Physicist responsible for performing the calibration.

(Q) Periodic Quality Assurance Checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to 105 CMR 120.436, which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of 105 CMR 120.436(Q)(1), quality assurance checks shall meet the following requirements:

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

(b) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 105 CMR 120.436(P)(1). They shall also state 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 105 CMR 120.436(P)(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the Qualified Medical Physicist shall be investigated and corrected before the system is used for patient irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Qualified Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in 105 CMR 120.436(P)(1);

(5) The registrant shall use the dosimetry system described in 105 CMR 120.434(C)(2) to make the quality assurance check required in 105 CMR 120.436(Q)(2);

120.436: continued

(6) The registrant shall have the Qualified Medical Physicist review and sign the results of each radiation output quality assurance check within 30 days of the date that the check was performed;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 105 CMR 120.436 are performed at intervals not to exceed 30 days;

(8) Notwithstanding the requirements of 105 CMR 120.436(Q)(6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 105 CMR 120.436(Q)(6) and (7) have been performed within one month period immediately prior to said administration;

(9) To satisfy the requirement of 105 CMR 120.436(Q)(7), safety quality assurance checks shall ensure proper operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance;

(b) Proper operation of the "BEAM-ON" and termination switches;

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

(d) Viewing systems;

(e) If applicable, electrically operated treatment room doors activated from inside and outside the treatment room;

(10) The registrant shall maintain a record of each quality assurance check required by 105 CMR 120.436(Q)(1) and (7) for three 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.

120.436: continued

(R) Operating Procedures.

(1) The therapeutic radiation machine shall not be used for irradiation of patients unless and until the requirements of 105 CMR 120.436(P) and (Q) have been met;

(2) Therapeutic radiation machines shall not be left unattended unless secured pursuant to 105 CMR 120.436(I)(5);

(3) Mechanical supporting or restraining devices shall be used when a patient must be held in position for radiation therapy;

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

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

(6) 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 105 CMR 120.211.

(S) Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 105 CMR 120.436 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten μSv (one mrem) per hour to ten mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 105 CMR 120.438.

120.437: Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)

(A) Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 105 CMR 120.437 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten Sv (one mrem) per hour to ten mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 105 CMR 120.438.

(B) Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

(1) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two 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% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

(2) Except for the area defined in 105 CMR 120.437(B)(1), the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

(3) For equipment manufactured after July 9, 1999, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 105 CMR 120.437(B)(1) through (B)(3) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

120.437: continued

(C) Leakage Radiation Through Beam Limiting Devices.

(1) Photon Radiation. The secondary collimators shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 2% (averaged over a one cm squared area) of the maximum absorbed dose on the central axis of the useful beam measured in a 100 $cm^2$ radiation field, or maximum available field size if less than 100 $cm^2$;

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

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

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

(3) Measurement of Leakage Radiation.

(a) 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 tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters;

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

(D) Filters/Wedges.

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

(2) If the absorbed dose rate information required by 105 CMR 120.437(I) relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

(3) 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:

(a) 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;

(b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(c) 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

(d) 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.

120.437: continued

(E) X-ray/Neutron Contamination of the Useful 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).

(F) Beam Monitors. All therapeutic radiation machines subject to 105 CMR 120.437 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

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

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

(3) The detector and the system into which that detector is incorporated shall meet the following requirements:

(a) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

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

(c) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

(d) For equipment manufactured after the effective date of these regulations, the design of the beam monitoring systems shall ensure that the:

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

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

(e) 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:

1. Maintain a reading until intentionally reset;

2. Have only one scale and no electrical or mechanical scale multiplying factors;

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

4. In the event of power failure, the beam monitoring information required in 105 CMR 120.437(F)(3)(e)3. 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.

(G) Beam Symmetry.

(1) Bent-beam linear accelerators subject to 105 CMR 120.437 shall be provided with auxiliary device(s) to monitor beam symmetry;

(2) The device(s) referenced in 105 CMR 120.437(G)(1) shall be able to detect field asymmetry greater than 10%; and

(3) The device(s) referenced in 105 CMR 120.437(G)(1) shall be configured to terminate irradiation if the specifications in 105 CMR 120.437(G)(2) can not be maintained.

(H) Selection and Display of Dose Monitor Units.

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

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

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

(4) For equipment manufactured after the effective date of these regulations, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

120.437: continued

(I) Air Kerma Rate/Absorbed Dose Rate. For equipment manufactured after October 6, 2006, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. [The radiation detectors specified in 105 CMR 120.437(F) may form part of this system.] In addition:

(1) The dose monitor unit rate shall be displayed at the treatment control panel;

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

(3) If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four Gy (400 rad); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 105 CMR 120.437(I)(2) and (I)(3) for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Agency.

(J) Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.

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

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

(3) For equipment manufactured after July 9, 1999, an indicator on the control panel shall show which monitoring system has terminated irradiation.

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

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

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

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

(2) 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;

(3) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

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

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

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

120.437: continued

(3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation modality which has been selected;
(4) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;
(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
(6) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(O) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
(1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
(2) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;
(3) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and
(4) For equipment manufactured after July 9, 1999, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

(P) Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:
(1) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
(2) The mode of operation shall be displayed at the treatment control panel;
(3) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;
(4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
(5) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1999:
(a) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10° of rotation or one cm of linear motion differs by more than 20% from the selected value;
(b) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5% from the dose monitor unit value selected;
(c) An interlock shall be provided to prevent motion of more than 5° or one cm beyond the selected limits during moving beam radiation therapy;
(d) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.
(e) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.
(6) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 105 CMR 120.437(J); and
(7) For equipment manufactured after July 9, 1999, an interlock system shall be provided to terminate irradiation if movement:
(a) Occurs during stationary beam radiation therapy; or
(b) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

120.437: continued

(Q) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of 105 CMR 120.439, the following design requirements are made:

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

(2) Control Panel. In addition to other requirements specified in 105 CMR 120.430, the control panel shall also:

(a) Be located outside the treatment room;

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

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

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

(3) Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient 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;

(4) 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;

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

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

(7) Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 105 CMR 120.221(A) and (B), interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

(8) Sliding Shielding Doors. Registrants with treatment rooms which utilize sliding shielding doors or other doors so massive that they may become jammed in the case of catastrophe will have in place an emergency plan to address such failure. In addition:

(a) Each door to a treatment room installed after July 9, 1999 will be equipped with an independent means of opening operable by a single able individual;

(b) Each sliding door installed after July 91, 1999 will be equipped with an electronic sensor which will immediately stop and disable the door closer (or reverse its motion) in the event of an imminent collision between the door and a person or object in its path.

(9) Emergency Cutoff Switches. At least three 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 105 CMR 120.437(K). 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;

(10) 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

(11) 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.

(R) Qualified Medical Physicist Support.

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

120.437: continued

(a) Full calibration(s) required by 105 CMR 120.437(T) and protection surveys required by 105 CMR 120.434(A);
(b) Supervision and review of dosimetry;
(c) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
(d) Quality assurance, including quality assurance check review required by 105 CMR 120.437(U)(5);
(e) Consultation with the authorized user in treatment planning, as needed; and
(f) Perform calculations/assessments regarding medical events.

(2) Radiation therapy facilities shall have a minimum of one half-time qualified medical physicist available on a regular, on going, basis. In addition, radiation therapy facilities will have a minimum of one full time equivalent qualified medical physicist for every 500 total patients per year.

(3) If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by 105 CMR 120.437(S) shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

(S) Operating Procedures.

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

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 105 CMR 120.434(A), 120.437(T) and (U) have been met;

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

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

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

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

(T) Acceptance Testing, Commissioning and Full Calibration Measurements.

(1) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 105 CMR 120.437 shall be performed by, or under the direct supervision of, a Qualified Medical Physicist.

(2) Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" or most current AAPM recommendation or most current AAPM published recommendations and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

(3) Full calibration shall include measurement of all parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" or the most current AAPM published recommendations and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" or most current AAPM recommendation or the most current AAPM published recommendations. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.

(4) The Qualified Medical Physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

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

120.437: continued

(b) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected 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 105 CMR 120.437(T)(4)(a).

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

(U) Periodic Quality Assurance Checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 105 CMR 120.437 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" or the most current AAPM published recommendations;

(2) To satisfy the requirement of 105 CMR 120.437(U)(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" or the most current AAPM published recommendations. Representative sampling shall include all referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been inter-compared within the previous 12 months with the dosimetry system described in 105 CMR 120.434(C)(1) to make the periodic quality assurance checks required in 105 CMR 120.437(U)(2);

(4) The registrant shall perform periodic quality assurance checks required by 105 CMR 120.437(U)(1) in accordance with procedures established by the Qualified Medical Physicist;

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

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

(b) 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 Qualified Medical Physicist within three treatment days; and

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

(6) Therapeutic radiation machines subject to 105 CMR 120.437 shall have safety quality assurance checks listed in the most currently published recommendations of reports of the AAPM Radiation Therapy Committee Task Group 40 at intervals not to exceed the frequencies recommended therein;

(7) To satisfy the requirement of 105 CMR 120.437(U)(6), safety quality assurance checks shall ensure proper operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance;

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

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

(d) Viewing systems;

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

(f) 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.

120.437: continued

(8) The registrant shall promptly repair any system identified in 105 CMR 120.437(U)(7) that is not operating properly; and

(9) The registrant shall maintain a record of each quality assurance check required by 105 CMR 120.437(U)(1) and (7) for three 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.

(V) Quality Assurance Checks for IMRT shall:

(1) Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans [Note: IMRT is a rapidly evolving modality and the QA program shall also evolve to handle new issues that arise.]; and

(2) Be performed in accordance with "Dosimetry Tools and Techniques for IMRT - The report of AAPM Task Group 120" (2010), or current AAPM Recommendation"; and

(3) Be performed in accordance with the manufacturer's contractual specifications.

120.438: Calibration of Survey Instruments

(A) The registrant shall ensure that the survey instruments used to show compliance with 105 CMR 120.430 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(B) To satisfy the requirements of 105 CMR 120.438(A), the registrant shall:

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

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately ⅓ and ⅔ of full-scale; and

(3) Calibrate automatically ranging digital display survey instruments at no less than one point on each decade and at no less than two points on one of these decades. These points should be at approximately ⅓ and ⅔ of the decade.

(C) To satisfy the requirements of 105 CMR 120.438(B), the registrant shall:

(1) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%; and,

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

(D) The registrant shall retain a record of each calibration required in 105 CMR 120.438(A) for three years. The record shall include:

(1) A description of the calibration procedure; and

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

(E) 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 105 CMR 120.438(D) shall be maintained by the registrant.

120.439: Shielding and Safety Design Requirements

(A) Each therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 105 CMR 120.211 and 120.221.

120.439: continued

(B) 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 105 CMR 120.440: *Appendix A*.

(C) Quality Assurance For Radiation Therapy Simulation Systems.

(1) Quality assurance for a conventional or virtual simulator shall include acceptance testing and periodic verification of system performance; and

(2) Be performed in accordance with "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No.40: AAPM Report No. 46" for a conventional simulator; or

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

120.440: 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 therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

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

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

B. Maximum design workload for the facility including total weekly radiation output, [expressed in gray (rad) or air kerma at one meter], total beam-on time 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. A facility blueprint/drawing indicating: scale [0.25 inch = one 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 therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 105 CMR 120.211.

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.

120.440: continued

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [ie: 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, please also identify the software used and the version/ revision date.

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

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120.440: continued

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 shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [*ie*: photon, electron]. The target to isocenter distance shall be specified.

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

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

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 [*ie*: room may be designed for six MV unit although only a four MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [*ie*: 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, also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, also 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 ten MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density 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 [*ie*: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility.