



NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
BOARD OF HEALTH

**Notice of Adoption of the Repeal and Reenactment of Article 175 of  
the New York City Health Code concerning radiation control.**

In accordance with §1043(b) of the New York City Charter (“Charter”) and pursuant to the authority granted to the Board of Health (“Board”) by Charter §558, a notice of public hearing and opportunity to comment on the repeal and reenactment of Article 175 of the New York City Health Code (“Health Code”) was published in the City Record on June 12, 2018 and a public hearing was held on July 16, 2018. The Department received 16 written comments from individuals or organizations<sup>1</sup> and 4 individuals spoke at the public hearing.

There was considerable overlap between the issues raised in the written comments and the public testimony. The vast majority of these comments were from the regulated stakeholder communities of hospital radiological personnel and medical physicist organizations, including the Greater New York Hospital Association, the Radiological and Medical Physics Society of New York, the New York State Radiological Society and the Greater New York Chapter of the Health Physics Society. In order to effectively address the range of concerns posed by their comments, the Department held a series of working group meetings with representatives from these stakeholder organizations following the public hearing.

Upon further review and assessment of the public comments and the stakeholder working group meetings, as well as on its own initiative, the Department has revised the adopted Article as summarized below:

- *Medical Physicists:* Commenters indicated that several provisions of the adopted Article were inconsistent with New York State licensure requirements concerning medical physicists. For example, the proposed Article could have been interpreted to allow non-licensed physicists to perform tasks that are within the scope of practice for licensed medical physicists, such as acceptance testing. The Department agreed with these comments and revised the proposal in response. The adopted Article now provides an updated definition for a Qualified Medical Physicist (QMP) and more accurately aligns with their scope of practice activities.
- *Shielding Plan Review:* Commenters objected to the proposed requirement for prior Department review of all shielding plans for radiation equipment installations (§175.45), stating it would unnecessarily hamper and delay facility construction and be impractical to administer. Also, a number of comments objected to a specific provision in §175.45 requiring x-ray installations to be located in a room with no windows. The Department agreed with the commenters on these points and deleted these provisions from the adopted Article. The Department also revised (but did not remove) the shielding plan review requirement for therapeutic radiation machines (§175.67).
- *Protective Garment Thickness:* Commenters objected to the proposed requirement for a protective garment thickness of 0.5 mm lead equivalent, rather than the typical 0.25 mm (see, e.g., §§175.48 and 175.53). The comments argued that the extra weight of the lead garments would cause practical difficulties for both patients and staff than could be justified by any extra protection afforded. The Department agreed with these comments and revised the adopted Article to require 0.25 mm lead equivalent protective garments.

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<sup>1</sup> Attached to the comment letter from the Radiological and Medical Physics Society of New York was a spreadsheet containing over 200 detailed bullet points identifying specific proposed Code sections suggesting text changes and clarifications. In the Department’s working group meetings with the stakeholders following the public hearing, these bullet points were agreed to serve as the basis of discussion.

- *Reliance on Guidelines:* A number of comments suggested that Article 175 utilize external agency guidance documents instead of delineating highly-prescriptive and detailed performance and quality assurance requirements for radiation-producing equipment. Generally, the Department did not agree with these comments and has maintained in the adopted Article the original level of detail for radiological equipment performance and quality assurance requirements. However, the Department has deleted certain detailed performance and operator requirements for mammography equipment (§175.54), as many of these requirements are promulgated by and enforced by the U.S. Food and Drug Administration pursuant to 21 CFR Subchapter I (Part 900).
- A number of comments objected to specific technical requirements, such as the parameters of a quality assurance test or equipment performance standard, stating that in practice such requirement was not realistic or achievable to comply with, or to verify compliance with the requirement as written. The Department agreed with many of these comments and revised certain of the adopted Article requirements accordingly.
- Many of the comments requested a change to a single narrow issue with the wording or regulation, for example, to fix a typographical error, add a definition, clarify the meaning of a requirement, or to reference updated standards documents. The Department agreed with many of these comments and revised the adopted Article accordingly.
- A number of comments noted that some definition or requirement was either redundant or possibly inconsistent between the equipment requirements and the radioactive materials requirements. In some instances, the Department agreed. For example, occupational dose limit requirements in §175.13 in Part II were revised to be consistent with occupational dose limits in the radioactive materials section in Part III. However, in many of these instances, the Department believed these comments reflected a misunderstanding of the structure of Article 175, i.e., that the radiation-producing equipment provisions (Part II) and the radioactive materials requirements (Part III) are generally structured and intended to be self-contained and independent of each other. To make this conceptual structure clearer to the regulated community, the Department added language to §175.01(a) in adopted Article 175 clarifying which requirements applied to equipment registrants (Part II) and which applied to materials licensees (Part III).

At its meeting on April 17, the Board adopted the following resolution.

### **Statement of Basis and Purpose**

Section 274 of the federal Atomic Energy Act of 1954 [42 USC §2021 et seq.] (“Atomic Energy Act”) authorizes “Agreement States” to regulate byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass. New York State is an “Agreement State” within the meaning of the Atomic Energy Act, and the New York City Department of Health and Mental Hygiene (“Department” or “DOHMH”) operates a component of the New York State Agreement. Under this Agreement State structure, the DOHMH, through its Office of Radiological Health (“ORH”), regulates radioactive material for medical, research and academic purposes within the five boroughs of New York City.

The New York State (NYS) Public Health Law §§225(5)(p) and (q) allows the NYS Commissioner of Health and the NYS Public Health and Planning Council to establish regulations with respect to ionizing radiation and nonionizing electromagnetic radiation and to authorize appropriate officers or agencies to register radiation installations, issue licenses for the transfer, receipt, possession and use of radioactive materials, other than special nuclear materials in quantities sufficient to form a critical mass, and render such inspection and other radiation protection services as may be necessary in the interest of public health, safety and welfare. The NYS regulations are set out in Part 16 of the NYS Sanitary Code.

The Sanitary Code, in 10 NYCRR §16.1(b)(3), allows New York City to establish its own radiation licensure requirements in place of State regulations, so long as the local requirements are consistent with Sanitary Code requirements.

The New York City Charter (“Charter”) Section 556(c)(11) authorizes the Department to supervise and regulate the public health aspects of ionizing radiation, the handling and disposal of radioactive wastes, and the activities within the city affecting radioactive material.

### ***Background***

Article 175 of the New York City Health Code (“Health Code”) applies to all radiation-producing equipment and radioactive material within NYC. The Article contains general provisions applicable to both radiation equipment registrants and radioactive materials licensees, and specific requirements for such equipment and materials. The purpose of Article 175 is to protect the public, as well as workers in radiation installation facilities, from the potential hazards of ionizing radiation. The Article’s requirements for radiation control reflects the coordination of radiation control activities among the U.S. Nuclear Regulatory Commission (“NRC”), the U.S. Food and Drug Administration, the NYS Department of Health and the NYS Department of Environmental Conservation, and other relevant city, state and federal agencies.

This reenacted Article 175 of the Health Code incorporates federal requirements contained in Title 10 of the Code of Federal Regulations (“CFR”) and reflects and is consistent with state regulations contained in the NYS Sanitary Code [10 NYCRR Part 16], and sets forth ORH-specific best practices requirements. By law, the City must maintain compatibility with applicable federal requirements, as well as consistency with applicable state regulations. The Health Code may, and Article 175 does, in certain instances, mandate more stringent requirements as to health and safety radiation control measures than those required by federal and state authorities, for example, requiring greater documentation of radioactive materials licensees’ quality assurance activities.

In NYC, there are about 6500 registered facilities with radiation-producing machines and 375 licensed sites with radioactive material for medical, academic and research purposes. Of the registered facilities, approximately 6440 are diagnostic X-ray facilities and 60 are therapeutic X-ray facilities. ORH inspects these facilities at varying frequencies depending on the type of usage. Current inspection fees are unchanged under the adopted Article.

### **Radiation equipment**

Prior to this rulemaking, Article 175 of the Health Code had not been significantly revised, particularly as to its radiation equipment requirements, since it was last reenacted in 1994. Similar to that last reenactment, the Board has based much of this reenacted text on the model code maintained by the Conference of Radiation Control Program Directors (CRCPD). The CRCPD is a 501(c)(3) nonprofit professional organization whose primary membership is made up of radiation professionals in state and local government that regulate the use of radiation sources in their jurisdictions. CRCPD’s mission is *"to promote consistency in addressing and resolving radiation protection issues, to encourage high standards of quality in radiation protection programs, and to provide leadership in radiation safety and education"*.<sup>2</sup> Since the reenactment of Article 175 in 1994, improved best practices have been developed and implemented for radiation control measures. Many of these measures are reflected in the current

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<sup>2</sup> See, <http://c.ymcdn.com/sites/www.crcpd.org/resource/collection/665D6792-2EB4-4AF6-8134-1173A394FE28/Constitution10-25-04.pdf> (describing the goals of the CRCPD to, among other things, promote radiological health in all aspects and phases and to promote and foster uniformity of radiation control laws and regulations).

CRCPD model code, which has provided the basis for much of the text related to radiation equipment in the adopted Article 175.

#### Radioactive materials

As noted above, Article 175 of the Health Code incorporates federal requirements from Title 10 of the CFR. New York State is an Agreement State with the U.S. NRC which means that the NRC has delegated authority to NYS to regulate radioactive material at non-reactor sites within its jurisdiction.

The New York State Agreement is comprised of the regulatory programs of three agencies:

1. the New York State Department of Health,
2. the New York State Department of Environmental Conservation, and
3. the New York City Department of Health and Mental Hygiene.

Under the NYS Agreement and § 16.1 of the State Sanitary Code, the Department, through its Office of Radiological Health (ORH), regulates radioactive material for medical, research and academic purposes within the five boroughs of New York City. Each Agreement State program is required to maintain compatibility with the NRC regulatory program. The NRC regulatory program utilizes Compatibility Categories to specify the type of wording to be used in the corresponding State program regulations.<sup>3</sup>

As noted above, the last significant revision of Article 175 requirements occurred over 20 years ago. Since then, NRC has made numerous updates of its requirements contained in Title 10 of the CFR. In order for the Department to maintain its compatibility status with the NRC regulatory program, each time the NRC has updated its regulations in Title 10 of the CFR, the Board has had to make corresponding updates to Article 175, which has been an inefficient and time-consuming process. In many instances, and because of the compatibility designations, the Board updated Article 175 by reproducing the actual CFR text directly into its requirements. The Board believes that continuing to update the Health Code rules this way is redundant and unnecessary and that it makes more sense to incorporate by reference the relevant CFR regulations, which will still provide the same legal force and effect as if the Board had actually reproduced such requirements in their entirety directly into Article 175. This incorporation by reference process avoids duplication and provides uniform, accurate guidance to the regulated community, as well as making makes Article 175 more manageable and user-friendly Article.

Accordingly, the Board has repealed and reenacted Article 175 primarily to:

- update the quality assurance requirements to reflect industry-wide best practices for the installation, operation and maintenance of both diagnostic and therapeutic radiation equipment required to be registered with the Department, and which is used for medical, academic and research purposes, and
- more efficiently adopt and enforce NRC requirements for the possession and use of radioactive materials required to be licensed by the Department by incorporating by reference applicable federal regulations contained in Title 10 of the CFR.

#### ***Statutory Authority***

This repeal and reenactment of Article 175 of the Health Code is promulgated pursuant to Charter Section 558. Sections 558(b) and (c) of the Charter empower the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 1043 of the Charter grants rule-making powers to the Department.

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<sup>3</sup> See, <https://scp.nrc.gov/procedures/sa200.pdf> (providing NRC compatibility categories and health and safety components assigned for determining whether an agreement state is maintaining a compatible radiation safety control program with NRC).

The adopted Article reads as follows:

“Shall” and “must” denote mandatory requirements and may be used interchangeably.

**RESOLVED**, that Article 175 of the New York City Health Code, concerning the regulation and control of radiation producing equipment and radioactive materials used for medical, academic and research purposes, as set forth in Title 24 of the Rules of the City of New York, is hereby REPEALED and a new Article 175 is REENACTED to read as follows:

## **ARTICLE 175 - RADIATION CONTROL**

### **PART I GENERAL PROVISIONS**

#### **§175.01 Applicability and communications.**

**(a) Applicability.**

(1) Except as provided in subdivision (b) of this section, this Article applies to any person who sells, transfers, assembles, receives, produces, possesses, or uses any radiation source in New York City.

(2) Part II of this Article (§§175.08 – 175.70) provides specific requirements for radiation equipment registrants and certified registrants.

(3) Part III of this Article (§§175.100 – 175.108) provides specific requirements for radioactive materials licensees.

**(b) Inapplicability.**

(1) This Article does not apply to any person with respect to any radiation source subject to regulation, as provided for by law, by the New York State Departments of Health or Environmental Conservation. This exclusion does not apply to the use of such sources in places where the general public may be exposed; or to persons with respect to radiation sources used at industrial or commercial establishments for the application of radiation to human beings.

(2) This Article does not apply to any common or contract carrier or any shipper operating within New York City to the extent that such carrier or shipper is subject to regulation as provided for by law by the U.S. Department of Transportation or other agencies of the United States or agencies of the State or City of New York, except for compliance with provisions relating to transportation of radioactive materials set forth in §175.106.

**(c) Communications.** Except as otherwise provided for in this Article, or as authorized by the Department, all applications, notifications, reports or other communications required by this Article must be addressed to the Department at:

NYC Department of Health and Mental Hygiene  
Office of Radiological Health  
42-09 28<sup>th</sup> St, CN 60  
Long Island City, New York 11101

#### **§175.02 Inspections and fees.**

**(a) Inspections.**

(1) Any radiation installation subject to the licensure or registration requirements of this Code shall be inspected periodically to ensure compliance with the provisions of this Article and the maintenance of radiation exposures as far below the limits set forth in this Article as practicable. Inspections shall be made at a frequency determined by the Department in its rules.

(2) Unless otherwise indicated, for newly-registered facilities, initial inspections shall be made at or near the time of the beginning of operation.

- (3) Inspections shall be made by the Department or, as the Department shall direct for dental and podiatric installations, by a Certified Radiation Equipment Safety Officer (CRESO) approved by the Department, to determine compliance with this Article and this Code.
  - (i) CRESOs must furnish an inspection report to the operator of the installation, in a form prescribed by the Department and signed by the person who made the inspection, and provide a copy thereof to the Department.
  - (ii) CRESOs must not charge or propose to charge a fee for an inspection above a fair and reasonable amount as determined by the New York State Department of Health.
- (4) Re-inspections or other appropriate follow-up activities will occur to ensure that any violation found during an inspection and not corrected at the end of such inspection is subsequently corrected.

(b) Inspection fees. Notwithstanding any other provision of this Code, the Department is authorized to charge the following inspection fees pursuant to section 225 of the New York State Public Health Law and the regulations promulgated thereunder:

- (1) For radiation equipment facilities required to have quality assurance programs pursuant to §175.12, the following inspection fees apply, where examination means the conduct of an x-ray patient exam by radiographic or fluoroscopic or a CT unit regardless of the number of patient exposures or x-ray exposure time:
  - (i) Hospital-inspected facilities:
    - (A) Large hospital (more than 40 tubes) base fee: \$1960.00
    - (B) Medium hospital (21–40 tubes) base fee: \$1585.00
    - (C) Small hospital (1–20 tubes) base fee: \$1290.00
  - (ii) Non-hospital facilities:
    - (A) Large (more than 2500 examinations per year) facility base fee: \$670.00
    - (B) Small (less than 2500 examinations per year) facility base fee: \$375.00
  - (iii) For each tube inspected at facilities identified in (i) or (ii) above of this paragraph, the following inspection fees apply in addition to the base fee:
    - (A) Radiographic: \$120.00
    - (B) Fluoroscopic: \$175.00
    - (C) Mammographic: \$295.00
    - (D) Dental: \$60.00
    - (E) All other: \$60.00
  - (iv) For radiation equipment facilities not required to have quality assurance programs pursuant to §175.12, the following inspection fees apply:
    - (A) First tube: \$170.00
    - (B) Each additional tube: \$60.00
- (2) For linear accelerator facilities, the following is the base fee: \$715.00
- (3) For facilities licensed to possess and use radioactive materials, the following inspection fees apply:
  - (i) Specific licenses authorizing teletherapy or gamma stereotactic radiosurgery, the following is the base fee: \$320.00
  - (ii) Specific licenses of limited scope authorizing medical use (except for teletherapy or gamma stereotactic radiosurgery)
    - (A) Base fee: \$610.00
    - (B) Per site fee: \$140.00
  - (iii) Specific licenses of limited scope authorizing non-human use
    - (A) Base fee: \$385.00
    - (B) Per site fee: \$160.00
  - (iv) Specific licenses of broad scope authorizing medical use (except for teletherapy or gamma stereotactic radiosurgery)
    - (A) Base fee: \$3515.00

- (B) Per site fee: \$140.00
- (v) Specific license of broad scope authorizing research and development (non-human use)
  - (A) Base fee: \$2450.00
  - (B) Per site fee: \$160.00

(c) Due date for inspection fees. Payment for inspection fees is due and payable 30 days after the billing date. Failure to pay any inspection fee may result in the suspension or revocation of a registration, certified registration or radioactive materials license.

**§175.03 Professional practitioners and related provisions.**

(a) Nothing in this Article shall limit any human use of radiation in diagnostic and therapeutic procedures, provided that with respect to human use of radioactive materials, such use is in accordance with a specific license or registration issued pursuant to this Article, or an exemption therefrom, or under a license issued by the New York State Department of Health or the United States Nuclear Regulatory Commission or an Agreement State.

(b) Each professional practitioner who treats or diagnoses any alleged or proven case of radiation illness or radiation injury to any individual, except that which can be expected in the normal course of radiation therapy and interventional fluoroscopic exams, must report to the Department in writing within 7 days of such treatment or diagnosis, the fact thereof and the full name, address, patient ID number, and age of such individual diagnosed or treated.

(c) No person other than a professional practitioner acting within the scope of their practice shall direct or order the application of radiation to a human being; nor shall any person other than a professional practitioner or a person working under the direction, order, or direct supervision of a professional practitioner apply radiation to a human being. Such direction, order to apply, application of, or administration of radiation must be within the lawful scope of, and in the course of, the practitioner's professional practice and must comply with the provisions of the license or other authorization of the professional practitioner under the New York State Education Law, or any applicable successor law and all regulations pertinent thereto, including, but not limited to provisions as to those parts of the human body and those persons which the professional practitioner may diagnose, analyze or treat or to which she may direct or order the application of, or apply, radiation, and provisions as to the type of radiation which the professional practitioner may use and the purpose for which the professional practitioner may use it.

(d) A professional practitioner shall be responsible for the supervision of any radiation employee who administers radiation to human beings to assure that each exposure is given consistent with expected medical benefit and in accordance with applicable standards or requirements relating to the practice for which such professional practitioner is licensed.

(e) A professional medical physicist shall be responsible for complying with the requirements of Article 166 of the New York State Education Law and applicable regulations, including Subpart 79-8 of Part 79 of Title 8 of the New York Codes, Rules and Regulations, or any applicable successor law or regulation.

(f) A licensed radiologic technologist must comply with applicable provisions of Article 35 of the New York State Public Health Law and Part 89 of Title 10 of the New York Codes, Rules and Regulations in order to provide services under this Article, including compliance with licensure requirements and the limitations, (if any, established by the New York State Department of Health, Bureau of Radiologic Technology) under which radiologic technologists and other persons, other than professional practitioners, may apply x-rays to human beings and all regulations pertinent thereto so as to assure maximum medical benefit with minimum radiation exposure.

**§175.04 Prohibited uses and activities.**

(a) Prohibited uses. The following are prohibited uses of radiation equipment:

- (1) Hand-held fluoroscopic screens.
- (2) Shoe-fitting fluoroscopic devices.
- (3) Intraoral fluoroscopy in dental examinations.
- (4) Photofluorographic equipment.

- (5) Equipment employing bare overhead or uninsulated conductors.
- (6) Non-image intensified fluoroscopes.
- (7) Capacity energy storage equipment used to image humans, effective July 1, 2021.
- (8) Intraoral dental x-ray machines operated at less than a measured 51 kVp effective July 1, 2021
- (b) Prohibited activities.
  - (1) No person shall operate x-ray equipment such that the useful beam is applied to human beings unless such individual is a professional practitioner or is otherwise authorized to operate x-ray equipment pursuant to state law.
  - (2) The sale, lease, transfer or loan of x-ray or fluoroscopic equipment or related supplies is prohibited, except to persons engaged in an occupation where such use is permitted or to institutions where such use is permitted. However, this restriction shall not apply to persons intending to use x-ray or fluoroscopic equipment and supplies solely for the application of radiation to other than human beings, nor to the acquisition of such equipment or supplies by wholesalers, distributors or retailers in the regular course of their trade or business.
  - (3) No person shall sell, lease, transfer, lend or install any radiation-producing equipment, or related supplies, unless such supplies or equipment when properly placed into operation or properly used will meet the requirements of this Article. A person who undertakes to repair such equipment must do so such that when it is placed in operation or properly used after the repair, the equipment will meet all applicable standards, including the requirements of this Article, for radiation protection and safety generally.
- (c) On or before July 1, 2022, portable or mobile x-ray equipment must only be used for examinations where it is impractical to transfer the patient to a stationary x-ray installation. Facilities are prohibited from using portable or mobile x-ray units in routine clinical x-ray exams; however, this shall not prohibit hospitals from using portable or mobile x-ray units in clinical exams in emergency room and trauma center locations and for in-house patients that are not ambulatory. Additionally, this shall not prohibit mobile or portable x-ray units in patient homes or long term health care facilities.

**§175.05 Vacating premises.**

No less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of their activities, each licensee or registrant must notify the Department in writing of their intent to vacate. When deemed necessary by the Department, the licensee or registrant must decontaminate the premises in such a manner as the Department may specify. Registrants must notify the Department of the disposition of the previously-registered equipment.

**§175.06 Modifications and variance.**

Upon either its own initiative or by application by an interested person, the Department may grant an exemption or variance request from any requirement in this Article if the Department finds that such exemption or variance will not result in an undue danger to life or property from radiation hazards. Any such application for modification and variance may be required to be supplemented and/or substantiated during Department review.

**§175.07 Enforcement.**

Notwithstanding anything to the contrary in this Code, the Department may:

- (a) by rule, regulation, order, license condition or registration condition, or otherwise as appropriate, impose requirements upon any person subject to this Article, in addition to those expressly set forth in this Article, as it deems appropriate or necessary to protect the public health and safety and to minimize danger to life or property from radiation hazards;
- (b) amend, suspend or revoke any license, registration or certified registration issued pursuant to this Article when it finds that any person holding such license, registration or certified registration is not in compliance with this Article, or other applicable laws, rules or regulations;



- (c) by order, require the removal through an authorized person, or the surrender to the Department, of any radiation source by any person who:
- (1) does not hold, or continue to hold, a valid license, registration or certified registration issued by the Department; or
  - (2) is not able or equipped, or who fails to observe with regard to such radiation source those radiation protection requirements of this Article, or who uses such radiation source in violation of this Article, Department order, or other applicable law, rule or regulation, or as set forth in a license, registration or certified registration issued by the Department. Upon such an order, such person shall be required to decontaminate any premises which may have been contaminated with radioactive material as a result of licensed or registered activities to radiation levels specified by the Department. Any expenses incidental to the transfer, surrender and decontamination shall be borne by the person responsible for the source.
- (d) Except where the protection of the public health requires immediate action, no Department actions described in subdivisions (b) and (c) of this section shall take effect until the person so affected is given reasonable notice and an opportunity to be heard by the Department.

## **PART II RADIATION EQUIPMENT**

### **§175.08 Definitions.**

The following definitions apply to Parts I and II (§§175.01 through 175.70) of this Article:

"Absorbed dose (D)" means the energy imparted by ionizing radiation per unit mass of irradiated material. The SI unit of absorbed dose is joule per kilogram or gray (Gy). The previously used ("traditional") unit of absorbed dose is the rad (1 Gy = 100 rad).

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

"Accelerator" means any machine capable of accelerating electrons, protons, or other charged particles in a vacuum and of discharging the resultant particulates or other radiation into a medium at energies usually in excess of 1 MeV.

"Accessible surface" means the external or outside surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer. This includes the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across the exterior edge of any opening.

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

"Air kerma (K)" means the kinetic energy released in air by ionizing radiation per mass of air. The SI unit of air kerma is joule per kilogram or gray (Gy).

"Air kerma rate (AKR)" means the air kerma per unit time.

"As low as reasonably achievable (ALARA)" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this Article as practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations in the public interest.

"Alert value" means a dose index (e.g., of CTDIvol (mGy) or DLP (mGy-cm)) that is set by the registrant to trigger an alert to the CT operator prior to scanning within an ongoing examination. The alert value represents a dose value well above the registrant's established range for the examination that warrants more stringent review and consideration before proceeding.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

"Analytical x-ray equipment" means equipment that generates (by electronic means) and uses ionizing radiation for the purpose of examining the microstructure of materials, i.e. diffraction and spectroscopy (including fluorescence).

"Annual" means at least once per year, at about the same time each year, plus or minus one calendar month.

"Attenuation block" means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

"Authorized user" means a licensed physician who is identified as a user of therapeutic equipment on a certified registration issued by the Department.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location a required quantity of radiation.

"Automatic exposure rate control (AERC)" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation per unit time.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. Background radiation does not include radiation from any regulated sources of radiation.

"Barrier" has the same meaning as "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.

"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.

"Beam port" means an opening on the x-ray apparatus designed to emit a primary beam. This does not include openings on baggage units.

“Biennial” means the test is done at least once every other year, at about the same time, plus or minus one calendar month.

"Biweekly" means at least once per two consecutive weeks (see "Weekly").

"Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

"Bone densitometry" means a noninvasive measurement of certain physical characteristics of bone that reflect bone strength. Test results are typically reported as bone mineral content or density and are used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

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

"Calibration" means the determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or the strength of a source of radiation relative to a standard.

"Cassette holder" means a device, other than a spot-film device, that supports or fixes the position of the cassette-based image receptor during a radiographic exposure.

"Cathode ray tube" means any device used to accelerate electrons for demonstration or research purposes, except where such cathode ray tube is incorporated into a television or display monitor that is subject to, and has met applicable federal radiation safety performance standards in 21 CFR §§1010 and 1020.10.

"Certified Radiation Equipment Safety Officer" (CRESO) means an individual who holds an unexpired certificate as a radiation equipment safety officer issued by the New York State Department of Health.

"CFR" or "10 CFR" means, except where a citation to a specific section is given, the regulations issued by the United States Nuclear Regulatory Commission contained in Chapter I of Title 10 of the Code of Federal Regulations.

"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 (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.

$\bar{x}$  = Mean value of observations in sample;

$x_i$  =  $i^{\text{th}}$  observation in sample;

$n$  = Number of observations sampled.

"Collimator" means a device for restricting the useful radiation in one or more directions.

"Computed radiography (CR)" means a digital x-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system. See also, the definition of "digital radiography."

"Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Computed tomography dose index (CTDI)" means the average absorbed dose, along the z-axis, from a series of contiguous irradiations. It is measured from one axial CT scan (one rotation of the x-ray tube), and is calculated by dividing the integrated absorbed dose by the nominal total beam collimation. The scattering media for CTDI consist of two (16 and 32 cm in diameter) polymethylmethacrylate (PMMA, e.g., acrylic or Lucite) cylinders of 14 cm length. The equation is:

$$CTDI_{100} = \frac{1}{NT} \int_{-50mm}^{50mm} D(z) dz$$

where:  $D(z)$  = the radiation dose profile along the z-axis.

$N$  = the number of tomographic sections imaged in a single axial scan. This is equal to the number of data channels used in a particular scan. The value of  $N$  may be less than or equal to the maximum number of data channels available on the system, and

$T$  = the width of the tomographic section along the z-axis imaged by one data channel. In multiple-detector-row (multi-slice) CT scanners, several detector elements may be grouped together to form one data channel. In single-detector-row (single-slice) CT, the z-axis collimation ( $T$ ) is the nominal scan width.

"Computed tomography (CT) scan" and "computerized axial tomography (CAT) scan" refer to an imaging procedure that uses x-rays to create cross-sectional images of the human body.

"Cone Beam Computed Tomography (CBCT)" is a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays and a cone-shaped x-ray beam (instead of fan-shaped) that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

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

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

"Controlled area" has the same meaning as "restricted area".

"Conventional simulator" means any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

"Cradle" means a removable device which supports and may restrain a patient above an x-ray table; or a device whose patient support structure is interposed between the patient and the image receptor during normal use; or which is equipped with means for patient restraint and which is capable of rotation about its long (longitudinal) axis.

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in this Article .

"CT dosimetry phantom" means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom must be a right circular cylinder of polymethyl-methacrylate of density  $1.19 \pm 0.01$  grams per cubic centimeter. Except for pediatric dose measurements, the phantom must be at least 14 centimeters in length and must 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 must provide means for the placement of a dosimeter 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.

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image:

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

where:

k = A constant, a normal value of 1,000 when the Hounsfield scale of CT number is used;

$\mu_x$  = Linear attenuation coefficient of the material of interest;

$\mu_w$  = Linear attenuation coefficient of water.

"CTDI<sub>100</sub>" means the accumulated multiple scan dose at the center of a 100-mm scan and underestimates the accumulated dose for longer scan lengths. It is thus smaller than the equilibrium dose. The CTDI<sub>100</sub> requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of CTDI<sub>100</sub>, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available "pencil" ionization chamber. CTDI<sub>100</sub> is acquired using a 100-mm long, 3-cc active volume CT "pencil" ionization chamber and one of the two standard CTDI acrylic phantoms (16 and 32 cm diameter) and a stationary patient table. The equation is:

$$CTDI_{100} = \frac{1}{NT} \int_{-50mm}^{50mm} D(z) dz$$

"CTDI<sub>vol</sub>" see "Volume Computed Tomography Dose Index (CTDI<sub>vol</sub>)"

"CTDI<sub>w</sub>" see "Weighted Computed Tomography Dose Index (CTDI<sub>w</sub>)"

"CT x-ray system" is technology that is used to perform CT scans and includes, but is not limited to: a control panel; image display device; gantry; x-ray tube; collimating device with filters; high voltage transformer; and, a data acquisition system. This includes CBCT systems that are used for other than dental x-ray scans.

"CT scanner" refers to technology used to perform and interpret CT scans and includes, but is not limited to: a control panel; gantry; high voltage generator; x-ray tube; table; and, display devices that are used for image interpretation.

"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" has the same meaning as "radiation detector."

"Declared pregnant worker" means a worker who has voluntarily informed their employer, in writing, of their pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant worker withdraws the declaration in writing or is no longer pregnant.

"Department" means the New York City Department of Health and Mental Hygiene.

"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.

"Diaphragm" means a device or mechanism by which the radiation beam is restricted in size.

"Digital radiography (DR)" means an x-ray imaging method or radiography which produces a digital rather than analog image. DR includes both computed radiography and direct digital radiography.

"Direct digital radiography (DDR)" means an x-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an x-ray image. Some DDR systems use a scintillator to convert x-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert x-rays directly to charge, which is stored on the thin-film transistor. See also the definitions of "computed radiography" and "digital radiography."

"Direct scattered radiation" or "direct scatter radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam. See also the definition of "scattered radiation."

"Direct personal supervision" means that the qualified practitioner must be present in the room when the procedure is being performed and is immediately available to provide assistance and direction throughout the performance of the procedure.

"Direct supervision" means a qualified practitioner must exercise general supervision and be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the qualified practitioner must be present in the room when the procedure is being performed.

"Dose" means the absorbed dose.

"Dose equivalent" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors, at the location of interest. Appropriate quality factors may be found in 10 CFR §20.2004.

"Dose area product (DAP) or "kerma-area product (KAP)" means the product of the air kerma and the area of the irradiated field and is typically expressed in Gy-cm<sup>2</sup>, so it does not change with distance from the x-ray tube.

"Dose length product (DLP)" means the indicator of the integrated radiation dose from a complete CT examination. It addresses the total scan length by the formula:

$$DLP (mGy-cm) = CTDI_{vol} (mGy) \times scan\ length (cm)$$

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

"Dose profile" means the dose as a function of position along a line.

"Effective dose equivalent" is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factors (WT) applicable to each of the body organs or tissues that are irradiated: HE =  $\Sigma(WT HT)$ .

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

"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.

"Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected exposure of an individual in excess of administrative or regulatory limits including the names and telephone numbers of individuals to be contacted.

"Equipment" means x-ray equipment, unless the specific context clearly indicates otherwise.

"Exposure rate" means exposure per unit of time, such as roentgen per minute. For purposes of this definition, "exposure" means the quotient dQ/dm, where dQ is the absolute value of the total charge of the ions of one sign produced in air and dm is the mass of air.

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

"Extremity" means hand, elbow, arm below the elbow, foot, knee and leg below the knee.

"Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more radiation machines are installed, located or used.

"Field of view (FOV)" means, in fluoroscopy, the diameter for circular image receptors or the diagonal for rectangular image receptors.

"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.

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

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

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes image receptors, 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.

"Fluoroscopically-Guided Interventional (FGI) procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

"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" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation. For computed tomography, "gantry" means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold or enclose these components within a computed tomography system.

"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.

"General supervision" means the procedure is performed under the overall direction and control of the qualified practitioner but who is not necessarily required to be physically present during the performance of the procedure.

"Gonad shield" or "gonadal shield" means a protective barrier for the ovaries or testes.

"Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. Also see "Absorbed Dose".

"Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced by one-half of its original value. For the purposes of



this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Hand-held x-ray equipment" or "hand-held x-ray system" means x-ray equipment that is designed to be hand-held during operation.

"Healing arts" means the use of radiation for purposes of medical diagnosis or treatment of humans or animals.

"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 to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern, in an analog fashion, into a corresponding light image of higher intensity.

"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.

"Individual monitoring devices" ""means devices designed to be worn by a single individual for the assessment of effective dose equivalent, such as film badges, thermo-luminescent dosimeters (TLDs), optically-stimulated luminescent dosimeters (OSLDs), pocket ionization chambers etc.

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

"Inspection" means an official examination or facility observation including, but not limited to, reviews of tests, reports, assessments, specifications, surveys and monitoring to determine compliance with applicable rules, regulations, orders, requirements and conditions enforceable by the Department.

"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 or engineered system that precludes access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

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

"Irradiation" means the exposure of 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  $dE_{tr}$  by  $dm$ , where  $dE_{tr}$  is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass  $dm$  of material; thus

K=dE<sub>tr</sub>/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." "Kerma-area product (KAP)" has the same meaning as "dose area product."

"Kilovolt (kV)" or "(kilo electron volt (keV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 volts in a vacuum. (Note: current convention is to use kV for photons and keV for electrons.)

"Kilovolt peak (kVp)" means the maximum value in kilovolts of the potential difference of a pulsating generator. When only one-half of the wave is used, the value refers to the useful half of the wave.

"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.

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

"Leakage radiation" means all radiation coming from within the source housing, except the useful beam or radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation and defined as follows:

- (a) 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 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;
- (b) 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; and
- (c) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Licensed radiologic technologist (LRT)" means an individual who is licensed and operates in compliance with Article 35 of the New York State Public Health Law and Part 89 of Title 10 of the New York Articles, Rules and Regulations, or any successor law or regulations.

"Licensee" means any person who is licensed by the Department in accordance with this Article or any person who possesses radioactive material which is subject to the licensure requirements of this ArticleArticle.

"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 visually appears to be approximately one-fourth of the maximum in the intersection.

"Limited-use system" means a personnel screening system that is capable of delivering an effective dose equivalent greater than 0.25  $\mu$ Sv (25  $\mu$ rem) per screening but cannot exceed an effective dose equivalent of 10  $\mu$ Sv (1 mrem) per screening. Limited-use systems require additional controls and documentation to ensure that annual individual dose limits required by H.12e, appropriate regulations or national standards are not exceeded.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential:

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

where:

$$\begin{aligned} V_n &= \text{No-load line potential; and} \\ V_l &= \text{Load line potential.} \end{aligned}$$

"mA" means milliamperes.

"mAs" means milliamperes second.

"Medical event" means a situation (except for an event that results from patient intervention) in which the administration of radiation from any radiation source results in:

- (a) a dose that differs from the prescribed dose by more than 0.05 Sv (5 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
  - (1) the total dose delivered differs from the prescribed dose by 20 percent or more; or
  - (2) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
- (b) a dose that exceeds 0.05 Sv (5 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 to the wrong individual or human research subject;
  - (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 percent or more of the dose expected from the administration defined in the written directive;
- (d) the administration of a CT or CBCT scan in which any of the following occur:
  - (1) a CT or CBCT scan is performed on the wrong person;
  - (2) a CT or CBCT scan is performed on the wrong body part, such that the patient dose from the scan to the wrong body part results in an effective dose equivalent exceeding 2.5 mSv (250 mrem), or 50 mSv (5 rem) to an organ or tissue;
  - (3) a CT or CBCT scan that results in damage to an organ, organ system or results in hair loss or erythema as determined by a physician; or
- (e) Any event resulting from intervention of a patient or human research subject in which the radiation from any radiation source results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

"Medical institution" means a "hospital" as defined in New York State Public Health Law §2801(1).

"Megavolt (MV)" or "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 1,000,000 volts in a vacuum. (Note: current convention is to use MV for photons and MeV for electrons.)

"Minor" means an individual less than 18 years of age.

"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.

"Mobile x-ray equipment" has the meaning ascribed to it in the definition of "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 spot film 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.

"Monitor unit (MU)" has the same meaning as "dose monitor unit."

"Monthly" means at least once per calendar month.

"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.

"Noise" in CT means the standard deviation of the fluctuations in CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S<sub>n</sub>) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

CS = Linear attenuation coefficient of the material of interest.

μ<sub>w</sub> = Linear attenuation coefficient of water.

s = Estimated [S]standard deviation of the CT numbers of picture elements in a specified area of the CT image.

"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.

"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.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the task. These procedures may include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures, which are related to radiation safety.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and

unlicensed sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material or implants and released from voluntary participation in medical research programs, or as a member of the public.

"Open-beam x-ray equipment" means an x-ray system in which the beam path could be entered by any part of the body at any time.

"Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment or machine-produced radiation for the purposes of medical therapy.

"Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

"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 parameter or condition continues to be valid.

"Personal supervision" means a qualified practitioner must exercise "general supervision" (as defined in this Article) and be present in the room or adjacent control area during the performance of the procedure.

"PBL" (See "Positive beam limitation").

"Person" means, notwithstanding §1.03 of Article 1 of this Article, any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing. For purposes of entities other than individual professional practitioners applying to this Department for the issuance of a radiation equipment registration or radioactive materials license, "person" shall mean only a principal officer, director or executive of the applying entity with authority to legally bind the applying entity to the obligations attendant to such registration or license.

"Phantom" means a test object either used to determine system characteristics or to evaluate system performance. The composition and design of a phantom varies based on the modality and test it is used for.

"Photostimulable storage phosphor (PSP)" means a material used to capture and store radiographic images in computed radiography systems.

"Picture Archiving and Communication System (PACS)" is a medical imaging technology that provides access to and storage for medical images from multiple modalities. It is comprised of an image acquisition system, display, network and data storage or archiving system.

"Picture element" means an elemental area of a tomogram.

"PID" has the same meaning as "position indicating device".

"Pitch" means the table incrementation, per x-ray tube rotation, divided by the nominal x-ray beam width at isocenter.

"Portable x-ray equipment" has the meaning ascribed to it in the definition of "x-ray equipment."

"Position indicating device (PID)" 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 beam-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.

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

"Primary beam" means the ionizing radiation coming directly from the radiation source through a beam port into the volume defined by the collimation system.

"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 "Protective barrier"

"Professional practice" means the practice of medicine, dentistry, podiatry, osteopathy, chiropractic or veterinary medicine.

"Professional practitioner" means any person licensed or otherwise authorized under the Education Law to operate a professional practice.

"Protective barrier" means a barrier of radiation absorbing material used to reduce radiation exposure.

The types of protective barriers are:

- (a) "primary protective barrier" or "primary barrier" means the material, excluding filters, placed in the useful beam.
- (b) "secondary protective barrier" or "secondary barrier" means the material which attenuates stray radiation.

"Protective garment" means an apron, glove, thyroid shield or other protective barrier worn by a professional practitioner or licensed radiographic technologist or patient made of radiation attenuating material, used to reduce radiation exposure.

"Protocol" means a collection of settings and parameters that fully describe an examination.

"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 one-half second.

"Qualified Medical Physicist (QMP)" means an individual who:

- (a) is licensed and maintains a current registration in accordance with Article 166 of the New York State Education Law and applicable regulations to practice any subspecialty of medical physics; and
- (b) for certified registrations, is listed on the certified registration and has been granted certification in a specific subfield of medical physics by an appropriate national certifying body and abides by the certifying body's requirements for continuing education.

"Quality Assurance (QA)" means a program providing for verification by written procedures, such as testing, auditing and inspection, to ensure that deficiencies, deviations, defective equipment, unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation equipment or radioactive material, are identified, promptly corrected and reported to the appropriate regulatory authorities as required.

"Quarterly" means an activity is done at least once in every third month, before the last business day or the end of the month, whichever comes first.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of this Article, ionizing radiation is an equivalent term. As used in this Article, radiation does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared or ultraviolet light.

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

"Radiation installation" means any location of radiation-producing equipment subject to this Article.

"Radiation Protocol Committee (RPC)" means the representative group of qualified individuals in a CT or FGI facility responsible for the ongoing review and management of CT or FGI protocols to ensure that exams being performed achieve the desired diagnostic image quality at the lowest radiation dose possible while properly exploiting the capabilities of the equipment being used. This committee and these functions may be subsumed under the registrant's radiation safety committee as described in §175.09(e).

"Radiation safety officer (RSO)" means an individual described in §175.10.

"Radiation source" means any radioactive material or any radiation equipment.

"Radiation source housing" or "x-ray tube housing" means that portion of an x-ray system which contains the x-ray tube or secondary target. Often the housing contains radiation shielding material or inherently provides shielding.

"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.

"Radioactive material" means any solid, liquid or gas which emits radiation spontaneously.

"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, permanent film or a digital image produced on a sensitive surface by a form of radiation other than direct visible light.

"Radiography" means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image after termination of the exposure; the process of creating radiographic images.

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

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

"Reference level" means dose levels in medical radio-diagnostic practices for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment.

"Registrant" means an individual or entity issued a certificate of registration, or certified registration, from the Department to operate registered radiation equipment.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor. One rem is equal to 0.01 sievert.

"Roentgen (R)" Means the special unit of exposure. One roentgen equals  $2.58E-4$  coulomb per kilogram of air.

"Restricted area" means an area, access to which is limited for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include any area used as residential quarters (but separate rooms in a residential building may be set apart as a restricted area).

"Safety device" means a device, interlock or system that prevents the entry of any portion of an individual's body into the primary x-ray beam or that causes the beam to shut off upon entry into its path.

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

"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 pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

"Scan time" means the time elapsed during the accumulation of x-ray transmission data for a single scan.

"Scattered radiation" or "scatter radiation" means radiation that has been deviated in direction or energy by passing through matter.

"Screening" means the application of x-ray radiation to diagnose a particular condition, as in the application of mammography x-rays to a female population to diagnosis the incidence of breast cancer.

"Sealed x-ray units" means any x-ray unit to which the Department affixes warning labels to in order to notify the registrant that the x-ray unit shall not be used for clinical x-ray exams.



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

"Semi-annual" means an activity is performed once within every sixth month before the end of the last business day or the end of the month, whichever comes first.

"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.

"Shutter" means a moveable device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly and is used to block the useful or primary beam emitted from an x-ray tube assembly.

"SI" means the International System of Units, usually abbreviated "SI" and refers to the modern metric system of measurement.

"SID" has the same meaning as "source-image receptor distance."

"Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previously used ("traditional") unit of dose equivalent is the rem. (1 Sv=100 rem).

"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 also the definitions of conventional simulator" and "virtual simulator."

"Skyshine" means radiation, such as neutrons and photons, generated by high energy proton accelerators over 10 MeV, which can be scattered by the atmosphere near the facility and result in public exposure as a scattered dose.

"Source" means the region or material from which the radiation emanates, for example, the focal spot of an x-ray tube.

"Source-image receptor distance (SID)" 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 cassette-based radiograph which is made during a fluoroscopic examination to permanently record a relevant image visible during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport 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.

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

"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

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

"Substantial radiation dose level (SRDL)" means an appropriately-selected dose used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient.

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

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

"Technique" means the settings selected on the control panel of the equipment.

"Technique chart" means a chart that lists the standard settings and positions for a given technique.

"Technique factors" means the conditions of operation displayed by the x-ray equipment, such as:

- (a) for capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);
- (b) for field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;
- (c) for CT equipment designed for pulsed operation, peak tube 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;
- (d) 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. Based on the manufacturer, the time-current product may be scaled by other scan parameters like the pitch; and
- (e) 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.

"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.

"Test" means the process of verifying compliance with an applicable standard or requirement.

"Therapeutic radiation machine" means photon or charged particle-producing equipment designed and used for external beam radiation therapy. For purposes of this Article, devices used to administer electronic brachytherapy or superficial photon or charged particle therapy shall also be considered therapeutic radiation machines.

"This Article" means Article 175 and all other parts of the New York City Health Code applicable to licensees and registrants or other persons subject to the provisions of Article 175, including but not limited to Articles 1, 3 and 5 of the Health Code.

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

"Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Total Effective Dose Equivalent (TEDE)" means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures; committed effective dose equivalent is a measure of dose that will be received from intake of radioactive material).

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

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

"Unintended" radiation dose in diagnostic or interventional x-ray means a patient radiation dose resulting from a human error or equipment malfunction during the procedure.

"Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam limiting device when the exposure switch or timer is activated to cause the 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 or other imaging modalities.

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

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

"Volume Computed Tomography Dose Index (CTDI<sub>vol</sub>)" means a radiation dose parameter derived from the CTDI<sub>w</sub> (weighted or average CTDI given across the field of view). The formula is:

$$CTDI_{vol} = (N)(T)(CTDI_w)/I$$

where:

N = number of simultaneous axial scans per x-ray source rotation,

T = thickness of one axial scan (mm), and

I = table increment per axial scan (mm).

Thus,

$$CTDI_{vol} = CTDI_w / \text{pitch}$$

"Warning device" means a visible or audible signal that warns individuals of a potential radiation hazard.

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

"Weighting factor W<sub>T</sub>" for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W<sub>T</sub> are:

### Organ Dose Weighting Factors

| <u>Organ or tissue</u> | <u>W<sub>T</sub></u>    |
|------------------------|-------------------------|
| <u>Gonads</u>          | <u>0.25</u>             |
| <u>Breast</u>          | <u>0.15</u>             |
| <u>Red bone marrow</u> | <u>0.12</u>             |
| <u>Lung</u>            | <u>0.12</u>             |
| <u>Thyroid</u>         | <u>0.03</u>             |
| <u>Bone surfaces</u>   | <u>0.03</u>             |
| <u>Remainder</u>       | <u>0.30<sup>1</sup></u> |
| <u>Whole Body</u>      | <u>1.00<sup>2</sup></u> |

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<sup>1</sup> 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

<sup>2</sup> For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor,  $w_T = 1.0$ , has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

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"Weekly" means at least once per week, where a week means seven consecutive days starting on Sunday.

"Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

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

"Weighted Computed Tomography Dose Index (CTDI<sub>w</sub>)" means the estimated average CTDI<sub>100</sub> across the field of view (FOV). The equation is:

$$CTDI_w = 1/3(CTDI_{100, \text{center}}) + 2/3(CTDI_{100, \text{edge}})$$

where, 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 or 32 cm acrylic phantom. CTDI<sub>w</sub> uses CTDI<sub>100</sub> and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

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

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

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

- (a) "mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
- (b) "portable x-ray equipment" means x-ray equipment designed to be hand-carried.
- (c) "stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

(d) "hand-held x-ray equipment" means x-ray equipment that is designed to be hand-held during operation.

"X-ray field" means that area of the intersection of the useful beam and any one of a 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 one-fourth of the maximum in the intersection. On recording devices that visualize the x-ray field, the perimeter can be taken to be the locus of points at which the brightness as it visually appears to the observer is approximately one-fourth of the maximum brightness in the intersection.

"X-ray high-voltage generator" or "x-ray 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, 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 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 bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

#### **§175.09 Radiation protection programs.**

Each registrant must at a minimum:

(a) develop, document and implement a radiation protection program commensurate with the scope and extent of their operations and sufficient to ensure compliance with the provisions of this Article.

The radiation safety program must include, but not be limited to, the following policies, procedures and activities:

(1) that the use of ionizing radiation within its purview is performed in accordance with existing laws and regulations; this requirement shall be deemed to be met by the registrant possessing a Quality Assurance Manual in accordance with §175.12 for the facility.

(2) that all persons are protected from radiation as required by this Article. A current and readily-accessible copy of Article 175 must be maintained by the registrant at the facility either in hard copy or electronic format.

(3) that upon discovery of a medical event, the registrant must follow the applicable requirements of §§175.25 and 175.26 concerning required notifications and reports.

(b) use, to the extent practical, procedures and engineering controls based upon 'best practice' radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA) below the limits specified in this Article.

(c) provide a radiation safety officer pursuant to §175.10 who shall be delegated authority to ensure the implementation of this radiation protection program.

(d) provide a quality assurance program pursuant to §175.12 for diagnostic and therapeutic uses of radiation-producing equipment operated under applicable provisions of this Article.

(e) for medical centers, hospitals and institutions of higher education, provide for a radiation safety committee to administer the radiation protection program. The radiation safety committee must include the facility operator or a person with the authority to act on behalf of the facility operator, and

representation from departments within the facility where radiation sources are used. The committee shall oversee all uses of radiation-producing equipment and radioactive materials within the facility, shall review the activities of the radiation safety officer and shall review the radiation safety program at least annually. The committee, or a subcommittee, shall oversee the administration of the required quality assurance program.

- (f) ensure that radiation equipment is used only for those procedures for which it is designed by individuals duly-licensed and fully-qualified to operate such equipment.
- (g) ensure that acceptance testing, by a QMP, is performed on all medical and chiropractic diagnostic equipment and radiation therapy treatment and planning equipment before the first use of such equipment on humans; and
- (h) at least every 12 months, review the radiation protection program content and its implementation.

**§175.10 Radiation safety officer.**

- (a) In addition to those requirements indicated in this section for specific categories, all radiation safety officers must:
  - (1) demonstrate knowledge of potential radiation hazards and emergency precautions; and
  - (2) have completed educational courses related to ionizing radiation safety or a radiation safety officer course; and
  - (3) demonstrate experience in the use and familiarity of the type of equipment used.
- (b) Specific duties of the radiation safety officer include, but are not limited to:
  - (1) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and to review them regularly to ensure that the procedures are current and conform with this Article;
  - (2) ensuring that individual monitoring devices are properly used by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by this Article;
  - (3) investigating and reporting to the Department each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this Article and each theft or loss of a source of radiation, determining the cause, and taking steps to prevent its recurrence;
  - (4) having a thorough knowledge of management policies and administrative procedures of the registrant and keeping management informed on a periodic basis of the performance of the registrant's radiation protection program;
  - (5) assuming control and having the authority to institute corrective radiation control actions, including shut down of operations if necessary, in emergency situations or unsafe conditions;
  - (6) ensuring that personnel are adequately trained in and complying with this Article, the conditions of the certificate of registration or certified registration, and the operating and safety procedures of the registrant; and
  - (7) maintaining all records as required by this Article.
- (c) For human use radiation equipment installations, the radiation safety officer must be:
  - (1) a QMP; or
  - (2) a professional practitioner practicing within the scope of such person's professional practice.
- (d) For human use radiation equipment installations requiring a certified registration pursuant to §175.41, the radiation safety officer must be:
  - (1) a QMP certified by the American Board of Health Physics, the American Board of Radiology or the American Board of Medical Physics in a branch of physics related to the type of use of radiation sources in the installation; or
  - (2) an authorized user named on the facility's certified registration issued by the Department.
- (e) For non-human use radiation equipment installations, the radiation safety officer must be:
  - (1) a veterinarian for veterinary installations; or
  - (2) a QMP; or

- (3) a person with equivalent training and experience as determined by the Department; or
- (4) a researcher or other individual determined by the institution as qualified by training and experience for installations using only x-ray diffraction and fluorescence analysis equipment.

**§175.11 Communications with workers.**

(a) Purpose and scope. This section establishes requirements for notices, instructions and reports by registrants to individuals engaged in activities under a registration. This section also sets forth options available to such individuals in connection with Department inspections of registrants conducted to ascertain compliance with the provisions of this Article and all applicable regulations and conditions stated on the registration regarding radiological working conditions. The regulations in this section apply to all persons who receive, possess, produce, use, own or transfer sources of radiation registered with the Department or are otherwise subject to this Article.

(b) Posting of notices to workers.

(1) Each registrant must post current copies of the following documents:

(i) Article 175 of this Article, or a notice providing an electronic link or internet address to a copy of Article 175 of this Article;

(ii) the registration or certified registration and the conditions or documents incorporated by reference into the certified registration and any amendments thereto;

(iii) the operating procedures applicable to the work under the registration or certified registration;

(iv) any notice of violation involving radiological working conditions, any proposed imposition of civil penalty or order issued pursuant to this Article and any response from the registrant.

(2) If posting of a document specified in this section is not practicable, the registrant may post a notice which describes the document and states where it may be examined.

(3) A current copy of the "Notice to Employees" prescribed by the Department must be posted by each registrant wherever individuals work in or frequent any portion of a restricted area.

(4) Documents, notices, or forms posted pursuant to this Article must appear conspicuously in a sufficient number of places to permit individuals engaged in work under the certified registration or registration to observe them on the way to or from any particular work location to which the document applies, and must be replaced if defaced or altered.

(5) Department documents posted pursuant to this section must be posted within 2 working days after receipt of the documents from the Department; the registrant's response, if any, must be posted within 2 working days after dispatch from the registrant. Such documents must remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

(c) Instructions to workers.

(1) All individuals working in or frequenting any portion of a restricted area must be:

(i) kept informed of the storage, transfer, or use of radiation producing equipment or of radiation in such portions of the restricted area;

(ii) instructed in the operating procedures applicable to work under the registration or certified registration, in the health protection problems associated with exposure to such radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed, and must be required to demonstrate familiarity with such precautions, procedures and devices;

(iii) instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of this Article, registrations or certified registrations for the protection of personnel from exposures to radiation occurring in such areas;

(iv) instructed of their responsibility to report promptly to the registrant on any condition which may lead to or cause a violation of this Article or the registration, or unnecessary exposure to radiation;

- (v) instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation; and
- (vi) advised as to the radiation exposure reports which workers must be given or may request pursuant to this section.
- (2) The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.
- (3) Instruction must be given before an individual begins work in a restricted area and at least annually thereafter.
- (4) Records documenting individual worker instruction must be maintained for inspection by the Department for 5 years.
- (d) Each registrant must inform each worker who is monitored pursuant to §175.17 of the worker's exposure to radiation or radioactive material as shown in records maintained by the registrant pursuant to §175.22. The information must be provided at least annually.
  - (1) Each registrant must make dose information available to workers as shown in records maintained by the registrant under the provisions of §175.24.
  - (2) The individual engaged or formerly engaged in activities controlled by the registrant may request his or her annual dose report.
    - (i) The report must include the dose record for each year the worker was required to be monitored pursuant to this Article. Such report must be furnished to the individual within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the registrant, whichever is later.
    - (ii) At the request of a worker who is terminating employment with the registrant in work involving exposure to radiation during the current year, each registrant must provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the registrant during the current year or fraction thereof.
- (e) Presence of representatives of registrants and workers during inspections.
  - (1) Each registrant must afford the Department at all reasonable times an opportunity to perform an inspection of machines, activities, facilities, premises and records required pursuant to this Article.
  - (2) During an inspection, Department inspectors may consult privately with workers. The registrant, or that person's representative, may accompany the Department inspectors during other phases of an inspection.
  - (3) If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the registrant must notify the inspectors of such authorization and must give the workers' representatives an opportunity to accompany the inspectors during the inspection of physical working conditions.
  - (4) Each worker's representative must be routinely engaged in work under control of the registrant and must have received instructions as specified in this section.
  - (5) Different representatives of registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.
  - (6) With the approval of the registrant and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, for example a consultant to the registrant or to the workers' representative, must be afforded the opportunity to accompany inspectors during the inspection of physical working conditions.
  - (7) Notwithstanding the other provisions of this subdivision, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area must be an individual previously authorized by the licensee or registrant to enter that area.



(f) Consultation with workers during inspections.

- (1) Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of this Article, certified registrations and registrations to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.
- (2) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violations of this Article, certified registration condition or registration, or any unnecessary exposure of any individual to radiation from sources of radiation under the registrant's control.

(g) Requests by workers for inspections.

- (1) Any worker or representative of workers who believes that a violation of this Article, registration, certified registration or license conditions exists or has occurred in work under a license or certificate of registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. Any such notice must be in writing, must set forth the specific grounds for the notice, and must be signed by the worker or representative of the workers. A copy must be provided to the licensee or registrant by the Department no later than at the time of inspection. The worker giving such notice may request that his or her name and the name of individuals referred to therein not appear in such copy or any record published, released, or made available by the Department, except for good cause shown.
- (2) If, upon receipt of such notice, the Department determines that the complaint meets the requirements set forth in paragraph (1) of this subdivision and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections performed pursuant to paragraph (1) of this subdivision need not be limited to matters referred to in the complaint.
- (3) No licensee, registrant, or contractor or subcontractor of a registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under this Article or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this Article.

(h) Inspections not warranted; informal review.

- (1) If the Department determines, with respect to a complaint under paragraph (1) of subdivision (g) of this section that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Deputy Commissioner for Environmental Health Services, who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position with the Deputy Commissioner of Environmental Health Services who will provide the complainant with a copy of such statement by certified mail.
- (2) Upon the request of the complainant, the Deputy Commissioner for Environmental Health Services may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the Deputy Commissioner for Environmental Health Services shall affirm, modify, or reverse the determination of the Department's Office of Radiological Health and

furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

- (3) If the Department determines that an inspection is not warranted because the requirements of paragraph (1) of subdivision (g) of this section have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of such paragraph.

**§175.12 Quality Assurance (QA) program requirements for diagnostic facilities.**

**(a) Purpose and scope.**

This section establishes quality assurance (as defined in §175.08) requirements for the use of machine-produced radiation or the radiation therefrom for diagnostic uses in the healing arts. The requirements in this section are intended to provide for the protection of the public health and safety and are in addition to, and not in substitution for, other applicable requirements in this Article.

**(b) Diagnostic facilities.**

- (1) Except dental, podiatric or veterinary facilities, each radiation installation performing diagnostic x-rays on humans must implement a quality assurance program that includes at a minimum:
- (i) the adoption of a facility- and equipment-specific QA manual containing written policies and procedures for radiation protection and describing the facility's quality assurance program. Policies and procedures must be consistent with the types of equipment and services provided including, but not limited to, identification of patients, use of gonadal or scoliosis shielding, personnel monitoring, protection of pregnant workers and patients and holding of patients. The quality assurance manual must describe the various processing, generator and systems QA tests appropriate for the types of equipment and services provided in sufficient detail to ensure that they will be performed properly;
  - (ii) the performance of QA tests and correction of deficiencies as specified in the QA manual;
  - (iii) the maintenance of equipment records for each diagnostic imaging system, containing test results, records of equipment repairs and other pertinent information;
  - (iv) requirements for performing appropriate testing as determined by the OMP after replacement or repair of equipment components that could adversely affect the resolution of the x-ray system and/or could cause an increase in patient dose;
  - (v) the provisions of a formalized in-service training program for employees including, but not limited to, quality assurance and radiation safety procedures;
  - (vi) the direct or indirect determination of radiation output at the point of skin entry for examinations routinely performed at the facility;
  - (vii) the provision of the information described in subparagraph (vi) of this paragraph to any patient upon request; and
  - (viii) the performance of and analysis of repeated, rejected or diagnostic events which are designed to identify and correct problems and to optimize quality.
- (2) Each registrant must maintain written records documenting QA and audit activities for review by the Department. Such records must be maintained by the registrant at least until after the next scheduled inspection is completed by the Department.
- (3) Diagnostic facility registrants required to maintain the facility-specific QA manual must comply with the requirements of this Article, as well as any registration conditions or Department directives or orders. Failure to maintain an up-to-date QA manual, or not adhering to this Article or Department directives or orders, shall be deemed as equivalent to the registrant not conducting a mandated QA program in violation of this section.
- (4) For hospital registrants only, a QMP, or the Radiation Safety Officer working with a QMP, must conduct oversight of its quality assurance programs, by:
- (i) auditing the QA program on an annual basis for compliance with the hospital's QA manual and the requirements of this Article; and

- (ii) submitting the annual audit report to the hospital radiation safety committee. The annual audit report must document the review of the following:
  - (A) the hospital's personnel monitoring program for compliance with this Article and hospital QA manual requirements; and
  - (B) the hospital's equipment QA testing, including frequency of testing, and resolution of equipment failures as to timely repair and testing, if any; and
  - (C) the calibration of radiation instruments used for equipment testing, if owned by the hospital; and
  - (D) the status of hospital employee training, both annual training requirements and Article requirements, for training hospital staff for specific equipment types; and
  - (E) review of all medical events that occurred in the hospital in relation to x-ray exams and an evaluation of the measures to prevent such re-occurrences and their effectiveness.
- (iii) The recommendations cited in the annual hospital audit report of subparagraph (ii) of paragraph (4) of this subdivision must be reviewed by the hospital radiation safety committee for a compliance determination. A written record of the hospital radiation safety committee decisions on the annual audit recommendations must be retained for review by the Department during periodic inspections.
- (5) Neonatal imaging. Neonatal intensive care units must develop a QA program which includes the following protocols:
  - (i) establishing a technique chart for neonatal imaging including, at a minimum, specific techniques for chest and abdomen, along with corresponding direct or indirect determination of entrance skin dose; and
  - (ii) an annual training program for Licensed Radiographic Technologists (LRTs) for conducting neonatal imaging; and
  - (iii) a protocol for the proper use of neonatal collimation; and
  - (iv) a protocol of gonadal shielding; and
  - (v) each facility must conduct an annual report on the compliance with the facility's neonatal QA program and forward such report to the facility radiation safety committee for review
- (6) Each registrant that conducts x-ray imaging of children must establish specific techniques at least for 1-year old, 5-year old and 10-year old children, specific to PA chest and abdomen x-ray studies. Additionally, the entrance skin exposure must be directly or indirectly determined for the latter studies and posted in the facility along with the technique chart wherever it is reasonable to expect that children of such an age group can be x-rayed.
- (c) X-ray film processing facilities. Registrants using analog image receptors (e.g., radiographic film) must have available suitable equipment for the handling and processing of radiographic film in accordance with the following provisions:
  - (1) Manually developed film shall be prohibited, except during dental surgical procedures when required.
  - (2) Automatic processors and other closed processing systems:
    - (i) automatic processors must be operated and maintained following manufacturer specifications.
    - (ii) films must be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film must be developed using the following chart:

| <u>Developer Temperature</u>                             |           | <u>Minimum Immersion Time*</u> |
|--|-----------|--------------------------------|
| <u>C°</u>  | <u>F°</u> | <u>Seconds</u>                 |
| <u>35.5</u>  | <u>96</u> | <u>19</u>                      |
| <u>35</u>  | <u>95</u> | <u>20</u>                      |
| <u>34.5</u>  | <u>94</u> | <u>21</u>                      |
| <u>34</u>  | <u>93</u> | <u>22</u>                      |
| <u>33.5</u>  | <u>92</u> | <u>23</u>                      |
| <u>33</u>  | <u>91</u> | <u>24</u>                      |
| <u>32</u>  | <u>90</u> | <u>25</u>                      |
| <u>31.5</u>  | <u>89</u> | <u>26</u>                      |
| <u>31</u>  | <u>88</u> | <u>27</u>                      |
| <u>30.5</u>  | <u>87</u> | <u>28</u>                      |
| <u>30</u>  | <u>86</u> | <u>29</u>                      |
| <u>29.5</u>  | <u>85</u> | <u>30</u>                      |
| <i>*Immersion time only, no crossover time included.</i> |           |                                |

- (3) Processing deviations from the above requirements of this section must 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).
- (d) Additional requirements for facilities using x-ray film.
- (1) Pass boxes, if provided, must be constructed to exclude light from the darkroom when cassettes are placed in or removed from the boxes and must incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.
  - (2) Darkrooms typically used by more than one individual must prevent accidental entry while undeveloped films are being handled or processed.
  - (3) Film must be stored in a cool, dry place and must be protected from exposure to stray radiation. Film in open packages must be stored in a light-tight container.
  - (4) Film cassettes and intensifying screens must be inspected periodically and must be cleaned and replaced as necessary.
  - (5) Outdated x-ray film past the manufacturer's expiration date must not be used for diagnostic radiographs of patients.
  - (6) The film and intensifying screen must be spectrally compatible.
  - (7) Facilities must maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every 6 months and after a change that may impact film fog.
- (e) X-ray film processing facilities other than dental, podiatry or veterinary must:

- (1) have a continuous and documented sensitometric QA program, including QA tests for speed, contrast and fog. These tests must be performed according to specifications of the manufacturer, a QMP, or a nationally-recognized organization.
  - (2) maintain a light-tight darkroom and use proper safelighting and safeguards such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not increase in optical density by more than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes must preclude fogging of the film.
  - (3) limit the base plus fog of unexposed film to an optical density less than 0.25 when developed by the routine procedure used by the facility.
- (f) Facilities using Computed Radiography (CR) or Direct Digital Radiography (DDR).
- (1) Commencing July 1, 2021, when exposure indicators are available, the facility must establish and document an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for a representative percentage of images taken must be compared to the established range. Consistent deviations from established ranges must be investigated, corrective actions taken as necessary, and results documented. This exposure range developed above must be posted at or near the x-ray console.
  - (2) Facilities must establish and follow an image QA program in accord with the recommendations of a QMP, the system manufacturer, or a nationally recognized organization
  - (3) Facilities other than dental, podiatric and veterinary, must quarterly complete phantom image evaluation using a phantom approved by a QMP or manufacturer. The analysis at a minimum must include: artifacts, spatial resolution, contrast/noise and exposure indicator constancy.
  - (4) In addition to the requirements of paragraphs (1) through (3) of this subdivision, CR facilities must establish a schedule of CR cassette erasure consistent with the manufacturer's recommendations.
- (g) Requirements for permitted radiographic facilities' Primary Diagnostic Monitors (PDM).
- (1) The requirements of this subdivision do not apply to dental, podiatric, veterinary, bone densitometer, nuclear medicine imaging and mammography facilities.
  - (2) The following definitions apply to this subdivision:
    - "Digital Imaging and Communications in Medicine (DICOM)" means a standard for handling, storing, printing and transmitting information in medical imaging.
    - "Documenting" means written, electronic or photographic records of testing performance.
    - "Maximum luminance" means the maximum light emission from the PDM front surface as measured by a calibrated photometer in units of candela/m<sup>2</sup>.
    - "Medical monitor" means any monitor that has both a built-in photometer and a QA software program allowing for routine QA tests to be performed.
    - "Monitor" means a display device that shows the results of a patient radiological image.
    - "Off-site PDM" means when the registrant contracts with a tele-radiology service for patient diagnosis of x-ray procedures. In such circumstances, the tele-radiology service must establish a PDM QA program that conforms to Department requirements.
    - "Primary Diagnostic Monitor (PDM)" means a monitor used to render a final diagnosis of a patient exam, including interpretations of patient mammograms. Monitors attached to digital units used as PDMs must have a QA program that complies with Department requirements, with the exception of monitors attached to bone densitometer units.
    - "Preliminary reads ("wet reads")" means a type of monitor that is exempt from PDM requirements. For purposes of this section, monitors used for wet reads, such as a monitor in a hospital emergency room used to make decisions about trauma patients and monitors of fluoroscopy units, are not considered PDMs.
    - "Registrant" means, for the purposes of the PDM QA requirements of this subdivision, the individual responsible for ensuring that a PDM QA program is implemented on site. This requirement still

applies if the registrant contracts with an off-site service, for example, tele-radiology service, for patient final diagnostic evaluations.

"Test pattern" means, for the purposes of PDM QA requirements, a pattern that is either a Society of Motion Picture and Television Engineers (SMPTE) test pattern, or the American Association of Medical Physicists (AAPM) Task Group (TG) #18 test pattern (TG 18 test pattern) or a test pattern from an applicable successor national standard.

(3) QA tests mandated for a PDM QA program. Each facility must make or have made QA tests to monitor equipment performance and maintain records of data collected. The facility must document their PDM quality assurance program in the facility's QA manual along with the results of the QA tests required. The QA tests required to be performed must include, at a minimum:

- (i) Visual test pattern evaluation (TG-18QC, SMPTE, or equivalent).
- (ii) DICOM calibration of the Grayscale Standard Display Function (GSDF) for each medical monitor on site at the registrant's location.
- (iii) Maximum luminance output.
- (iv) Minimum luminance output.
- (v) Luminance ratio of maximum to minimum.
- (vi) Evaluation of viewing conditions.

### **§175.13 Occupational dose limits.**

(a) The registrant must control the occupational dose to individual adults to the following dose limits:

(1) an annual limit, which is the more limiting of:

- (i) the total effective dose equivalent being equal to 0.05 sievert (5 rem); or
- (ii) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 sievert (50 rem).

(2) the annual limits to the lens of the eye, to the skin, and to the extremities which are:

- (i) a lens dose equivalent of 0.15 sievert (15 rem); and
- (ii) a shallow dose equivalent of 0.5 sievert (50 rem) to the skin or to any extremity.

(b) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Department. The assigned deep dose equivalent shall be for the portion of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure:

- (1) when a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in §175.17(b)(4), the effective dose equivalent for external radiation shall be determined as follows: when only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent value divided by 5.6 shall be the effective dose equivalent for external radiation; or
- (2) when individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(c) The registrant must reduce the dose that an individual may be allowed to receive in the current year by the occupational dose amount received while employed elsewhere during the current year.

(d) The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits for adult workers specified in this section.

(e) Dose to an embryo/fetus.

- (1) The registrant must ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant worker, does not exceed 5 mSv (0.5 rem).
- (2) The registrant must review exposure history and adjust working conditions so as to avoid a monthly exposure of more than 0.5 mSv (50 mrem) to a declared pregnant worker.
- (3) The dose to an embryo/fetus shall be the sum of:
  - (i) the deep dose equivalent to the declared pregnant worker; and
  - (ii) the dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant worker.
- (4) If, by the time the worker declares pregnancy to the registrant, the dose equivalent to the embryo/fetus is found to have exceeded 5 mSv (0.5 rem), or is within 0.5 mSv (50 mrem) of this dose, the registrant shall be deemed to be in compliance with this subdivision if the additional dose to the embryo/fetus does not exceed 0.5 mSv (50 mrem) during the remainder of the pregnancy.

**§175.14 Dose limits for individual members of the public.**

- (a) Each registrant must conduct operations so that:
  - (1) the total effective dose equivalent to individual members of the public from the registered operation, does not exceed 1 millisievert (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with the requirements of 10 CFR Part 35, or from voluntary participation in medical research programs.
  - (2) the dose in any unrestricted area from external sources does not exceed 0.02 millisievert (2 mrem) in any one hour.
- (b) If the registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

The Department may impose additional restrictions on radiation levels in unrestricted areas by registration condition.

**§175.15 Compliance with dose limits for individual members of the public.**

- (a) The registrant must conduct surveys of radiation levels in unrestricted areas.
- (b) The registrant must show compliance with the annual dose limit in §175.14 by demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit.

**§175.16 Surveys and monitoring.**

Each registrant must conduct surveys to comply with this Article to evaluate the magnitude and extent of radiation levels and potential radiological hazards.

- (a) The registrant must ensure that instruments and equipment used for quantitative radiation measurements, for radiation survey purposes, are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in this Article.
- (b) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose, must be processed and evaluated by a dosimetry processor:
  - (1) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology; and
  - (2) approved in this accreditation process for the type of radiation or radiations included in the National Voluntary Laboratory Accreditation Program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- (c) The registrant must ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

(d) No registrant shall remove an exposure from an individual's exposure record without prior authorization from the Department. To remove an exposure from an individual's exposure record, the registrant must provide the following documentation to the Department:

- (1) a letter to the Department indicating the person whose exposure is to be removed along with an investigation into the possible causes for the exposure and a signed note from the individual concurring with the removal of the exposure; and
- (2) a copy of the individual's personnel monitoring report along with the investigation the personnel monitor vendor conducted of the exposure. For occurrences where the personnel monitor vendor indicates that a static exposure occurred on the personnel monitoring report sent to the registrant, the latter investigation is waived.

**§175.17 Conditions requiring individual monitoring of external occupational dose.**

(a) Each registrant must monitor exposures from sources of radiation to demonstrate compliance with the occupational dose limits of this Article.

(b) Each registrant must supply and require the use of individual monitoring devices by:

- (1) adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in §175.13; and
- (2) minors and declared pregnant workers likely to receive, in 1 year from sources external to the body, a deep dose equivalent in excess of 10 percent of any of the applicable limits in §175.13; and
- (3) declared pregnant workers likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 millisievert (0.1 rem); and
- (4) all individuals working with medical fluoroscopic equipment, including equipment operators and other staff physically present at the treatment location who are not behind protective shielding.
- (5) All personnel monitoring devices used to monitor fluoroscopic radiation exposures must be returned to the vendor for processing on a monthly basis, except that for individuals only working with mini-C arm fluoroscopy equipment, the monitoring devices must be returned at least quarterly.
- (6) The registrant must submit the dosimeter for processing with due diligence and never after the time specified by the manufacturer of the dosimeter. Where dosimeters are processed on the registrant's premises, the registrant must require monitored individuals to read their monitors monthly.

**§175.18 Location of individual monitoring devices.**

Each registrant must ensure that individuals who are required to monitor occupational doses in accordance with §175.13 use individual monitoring devices as follows:

- (a) an individual monitoring device used for monitoring the dose to the whole body must be worn at the unshielded location of the whole body likely to receive the highest exposure. For individuals wearing a protective apron, when only 1 individual monitoring device is used, it must be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used for the same purpose, it must be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant worker.
- (b) an individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant worker, pursuant to §175.17, must be located at the waist under any protective apron being worn by the worker;
- (c) an individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with §175.13, must be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;
- (d) an individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with §175.13, must be worn on the extremity likely to receive the highest exposure. Each



individual monitoring device must be oriented to measure the highest dose to the extremity being monitored.

**§175.19 Labeling radiation machines.**

Each registrant must ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

**§175.20 Records of radiation protection programs.**

- (a) Each registrant must maintain records of the radiation protection program, including audits, records of surveys, calibrations, maintenance and modifications (e.g., major software and hardware upgrades) performed on the x-ray system and a copy of all correspondence with the Department regarding the x-ray system.
- (b) Unless otherwise indicated, the registrant must retain the records required by subdivision (a) of this section for a minimum of 5 years after the record is made, except that model and serial numbers of all major components and user's manuals for those components, including software, must be maintained for the life of the system.

**§175.21 Determination and records of prior occupational dose.**

- (a) For each individual who is likely to receive, within 1 year, an occupational dose requiring monitoring pursuant to §175.17, the registrant must:
  - (1) determine the occupational radiation dose received during the current year; and
  - (2) request in writing the records of cumulative occupational radiation dose.
- (b) In complying with the requirements of this section, a registrant may:
  - (1) accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and
  - (2) accept, as the record of cumulative radiation dose, an up-to-date Department form or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant; and
  - (3) obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, telegram, facsimile, other electronic media or letter. The registrant must request a written verification of the dose data if the authenticity of the transmitted report cannot be established.
- (c) The registrant must record the exposure history, with all the following required information:
  - (1) the form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the registrant obtains reports, the registrant must use the dose shown in the report. For any period in which the registrant does not obtain a report, the registrant must place a notation in the record or equivalent indicating the periods of time for which data are not available.
  - (2) for the purposes of complying with this requirement, registrants are not required to partition historical dose between external dose equivalent and internal committed dose equivalent. Occupational exposure histories that do not include effective dose equivalent may be used in the absence of specific information on the intake of radionuclides by the individual.
- (d) If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant shall assume:
  - (1) in establishing administrative controls for the current year, that the allowable dose limit for the individual is reduced by 12.5 millisievert (1.25 rem) for each quarter for which records were

unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(2) that the individual is not available for planned special exposures.

- (e) The registrant must retain the records required by this section until the Department terminates each pertinent registration requiring this record. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.
- (f) Upon termination of the registration, the registrant must permanently store such records, or must make provision with the Department for transfer of such records to the Department.

**§175.22 Records of individual monitoring results.**

- (a) Recordkeeping. Each registrant must maintain records of doses received by all individuals for whom monitoring is required by this Article. These records must include, when applicable, the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities.
- (b) The registrant must make entries of the records of individual monitoring results at intervals not to exceed 1 year.
- (c) The registrant must maintain individual monitoring results in clear and legible records containing all required information by the Department.
- (d) The registrant must maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant worker. The declaration of pregnancy, including the estimated date of conception, must also be kept on file, but may be maintained separately from the dose records.
- (e) The registrant must retain each required form or record until the Department terminates the certified registration or registration requiring the record.

**§175.23 Records of dose to individual members of the public.**

- (a) Each registrant must maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public.
- (b) The registrant must retain the records of dose to individual members of the public until the Department terminates each pertinent registration or certified registration requiring the record.

**§175.24 Form of records.**

- (a) Each record required by this Article must be legible throughout the specified retention period and, where required, must be on the appropriate Department form. The record must 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 producing a clear copy throughout the required retention period, or 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.
- (b) The registrant must maintain adequate safeguards against tampering with and loss of records.
- (c) The discontinuance or expiration of authorized activities does not relieve any person who possesses any radiation source of responsibility for retaining all records required by this Article.

**§175.25 Notification and reporting of events.**

- (a) Immediate notification. Notwithstanding other requirements for notification in this Article, each registrant must immediately report each unintended event involving a source of radiation possessed by the registrant that may have caused or threatens to cause any of the following conditions for an individual to receive:
  - (1) a total effective dose equivalent of 0.25 sievert (25 rem) or more; or
  - (2) a lens dose equivalent of 0.75 sievert (75 rem) or more; or

- (3) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 sievert (250 rem) or more.
- (b) Twenty-four hour notification. Each registrant must, within 24 hours of discovery, report to the Department:
  - (1) Any unintended event involving a registered source of radiation possessed by the registrant that may have caused, or threatens to cause, any of the following conditions for an individual to receive in a period of 24 hours:
    - (i) a total effective dose equivalent exceeding 0.05 sievert (5 rem); or
    - (ii) a lens dose equivalent exceeding 0.15 sievert (15 rem); or
    - (iii) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 sievert (50 rem).
  - (2) Any medical event as defined in §175.08.
  - (3) An event in which equipment is disabled or fails to function as intended when:
    - (i) the equipment is required by regulation or a condition of a registration to prevent exposures exceeding regulatory limits, or to mitigate the consequences of an accident; or
    - (ii) the equipment is required to be available and operable when it is disabled or fails to function; and
    - (iii) no redundant equipment is available and operable to perform the required safety function.
- (c) Registrants must make the notification required by subdivisions (a) and (b) of this section by initial contact by telephone to the Department and must confirm the initial contact by letter, e-mail or facsimile to the Department. To the extent that the information is available at the time of notification, the information provided in these notifications must include:
  - (1) the caller's name and call back telephone number;
  - (2) a description of the event, including date and time;
  - (3) the exact location of the event;
  - (4) any personnel radiation exposure data available.
- (d) Written reports. Each registrant must submit a written report to the Department within 30 days after learning of:
  - (1) events for which notification is required by §175.25 (a) through (b);
  - (2) doses in excess of any of the following:
    - (i) the occupational dose limits for adults in §175.13;
    - (ii) the occupational dose limits for a minor in §175.13;
    - (iii) the limits for an embryo/fetus of a declared pregnant worker in §175.13;
    - (iv) the limits for an individual member of the public in §175.14; or
    - (v) any applicable limit in the registration;
  - (3) levels of radiation in:
    - (i) a restricted area in excess of applicable limits in the registration; or
    - (ii) an unrestricted area in excess of 10 times the applicable limit set forth in this Article or in the registration, whether or not involving exposure of any individual in excess of the limits in §175.13.
- (e) Contents of written reports. Each report required by this section must include, as appropriate:
  - (1) a description of the event, including the probable cause of the elevated exposures or dose rates and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned
  - (2) estimates of each individual's dose;
  - (3) the levels of radiation involved; and
  - (4) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards and associated registration conditions.

- (5) Each report filed pursuant to this section must include for each occupationally overexposed individual: the name, employee ID number if available, and date of birth. With respect to the limit for the embryo/fetus in §175.13, the identifiers should be those of the declared pregnant worker. The report must be prepared so that individually-identifiable information is stated in a separate and detachable portion of the report and not otherwise revealed.
- (f) Any written report of a medical event as defined in §175.08 must include a calculation of the resulting radiation dose that was delivered in error, and be forwarded to the registrant's radiation safety committee or the radiation safety officer for their action. The report must be maintained on-site, or readily available for review by the Department during inspection.

**§175.26 Reports to individuals of exceeding dose limits.**

- (a) When a registrant is required to report to the Department any exposure of an identified occupationally-exposed individual, or an identified member of the public to radiation, the registrant must also provide a copy of the report submitted to the Department to the individual. This report must be transmitted at a time no later than the transmittal to the Department.
- (b) When necessary or desirable in order to aid in determining the extent of any individual's exposure to radiation subsequent to any radiation accident, or incident, the registrant must make available to such individual appropriate medical evaluation services or appropriate tests and furnish the Department a copy of each report of such evaluation or test.

**§175.40 Registration of radiation machine facilities.**

- (a) Registration required. Prior to establishing, maintaining or operating any radiation installation with any radiation equipment in operable condition, or prior to installing such equipment which is intended to be used, the owner, operator or person in charge of such installation must have obtained a current certificate of registration or, for a therapeutic radiation machine as defined in and subject to the requirements of this Article, a certified registration from the Department. Unless otherwise authorized by the Department, no one shall apply x-rays to diagnose or treat any patient's medical condition at a facility that does not possess a current, non-expired certificate of registration issued from the Department. This subdivision does not prohibit the installation of radiation-producing equipment at a facility solely for testing purposes by a QMP, or for testing necessary to prepare reports required for registration.
- (b) Application for a certificate of registration must be made to the Department in a manner prescribed by the Department.
- (c) Registered facilities at which the owner, operator or location will be changed must apply for a new registration prior to such change.
- (d) The applicant for registration for all facilities mandated to have a quality assurance program pursuant to §175.12(b) must:
- (1) submit a completed application form and required supporting documents, if any; and,
  - (2) submit a report prepared by a QMP detailing the results of initial quality assurance tests conducted on all radiation-producing equipment in the facility. In this context, the initial quality assurance tests shall be the sum of all quality assurance tests mandated to be conducted for the facility type at any frequency (for example all daily, monthly, and annually required tests etc.). Also, a radiation protection survey must be conducted and submitted for each room housing a radiographic unit.
  - (3) designate a radiation safety officer on each application form.
  - (4) designate a professional practitioner responsible for directing the operation of radiation machines on each healing arts application. The signature of the administrator, president or chief executive officer will be accepted in lieu of a professional practitioner's signature if the facility has more than one professional practitioner (for example, hospitals, large clinics, or multi-practitioner practices).

- (e) An application for registration may be denied for any basis provided in this Article.
- (f) The Department will not grant a facility's registration until such time as the report described in §175.40(d)(2) contains all mandated quality assurance tests and all corrective actions that may be required therefrom have been completed as determined by the Department.

  - (1) Upon completion of the review process for the submitted quality assurance tests by the facility, if reasons exist to refuse authorization to register the facility's radiation-producing equipment for clinical usage, the facility shall be notified of the reasons for such a decision by the Department in writing and shall be provided an opportunity to respond.
  - (2) If requested, the applicant must file all responsive information that the Department finds deficient within 30 days of the Department's request, or the application will be deemed abandoned and void. In the latter case, the applicant must refile the application.
- (g) Dental, podiatric and veterinary facilities.

  - (1) All new dental, podiatric, and veterinary facilities without a current certificate of registration must apply for a new registration prior to the beginning of facility operation. All new dental, podiatric and veterinary facilities shall be prohibited from commencing diagnostic clinical examinations until such time that the facility has either received a certificate of registration from the Department for all such equipment, or the Department has performed a physical inspection of the facility and any deficiencies identified have been corrected, or the Department has reviewed and approved the QMP or CRESO reports to determine that all radiological equipment to be used are operating as intended.
  - (2) A dental facility possessing a Cone Beam Computed Tomography (CBCT) unit must maintain a quality assurance program for such CBCT unit and shall register such CBCT unit with the Department in accordance with subdivision (d) of this section prior to conducting clinical exams with such CBCT unit.
- (h) Renewal registrations. Facilities with current, valid certificates of registration must apply for renewal at least 30 days prior to the expiration of such certificate of registration. Facilities with a certificate of registration that is suspended or revoked, or where the installation is discontinued on or before the expiration of the certificate of registration, may not apply for renewal.
- (i) Fees. Fees for each registration and certified registration shall be paid pursuant to §§5.07 and 5.09(f) of Article 5 of this Code.
- (j) Duration of registrations. A certificate of registration shall be issued for a limited period of time extending from the date of issuance to the date of expiration as specified on the certificate of registration. Registration validity shall not exceed 2 years except that the Department, at its discretion, may issue a certificate of registration for a longer period of time in order to stagger expiration dates for administrative purposes and may charge a proportionate increase in fees to reflect this.
- (k) Expiration of registrations.

  - (1) The registration issued for a radiation installation shall expire and may be required to be surrendered to the Department upon:

    - (i) failure to renew by the expiration date specified on the certificate of registration; or
    - (ii) revocation by the Commissioner; or
    - (iii) a change of the person to whom the certificate of registration is issued; or
    - (iv) a change in address of the radiation installation if it is not a mobile unit; or
    - (v) a change in the name of the installation; or
    - (vi) the discontinuance of the installation.
  - (2) Notwithstanding paragraph (1) of this subdivision, if a registrant whose registration has expired indicates in writing to the Department that they are in the process of completing and files a proper registration application renewal form with the Department, or properly files for a new and superseding registration, at least 30 days prior to the stated expiration date, such registration shall not be deemed to have expired until the Department has decided upon such renewal application.

- (l) Suspension and revocation of registrations. A registration may be suspended or revoked for any basis provided in this Article, including pursuant to §5.17 of Article 5 of this Code, or if the Commissioner finds that:
  - (1) the information submitted in the application is materially incorrect or incomplete;
  - (2) the installation is, has been or will be established, maintained, or operated in violation of this Article, or any other applicable law, rule, regulation, order or condition;
  - (3) the certificate of registration has not been issued correctly; or
  - (4) the fees for registration or inspections and adjudicated fines have not been paid as required.
- (m) A certificate of registration issued for a radiation installation must be posted in accordance with the provisions of §5.15 of Article 5 of this Code. If posting is not practicable, the registrant may post a notice stating where it may be examined.
- (n) The operator of a radiation installation must keep its registration information current by reporting to the Department of any change affecting the registration within 10 days of such change.
- (o) The registration issued to a facility does not imply endorsement or approval by the Department and must not be used to advertise or promote business.
- (p) A certificate of registration or certified registration is not transferable or assignable.
- (q) The Department may refuse to issue, or may suspend or revoke, a certificate of registration for any facility that refuses to allow the Department to conduct an inspection of all of the facility's x-ray equipment or records or refuses or is unable to correct any violations of this Article noted during an inspection.
- (r) Exemptions. Registration with the Department is not required for:
  - (1) radiation equipment constructed so that it cannot emit radiation at a level greater than 0.5 milliroentgen per hour, measured 5 cm (2 in.) from any accessible surface thereof, and averaged over an area of 10 cm<sup>2</sup> (1.55 in<sup>2</sup>) provided, however, that such exemption shall not apply to the testing or servicing of such equipment during its production; or
  - (2) radiation equipment during its storage, shipment, retail sale or other similar use (but not including installation) during which such equipment is not connected to a voltage source and does not emit radiation, provided however, that such equipment is not exempt from the labeling requirement of §175.20.

**§175.41 Certified registration for therapeutic radiation machines.**

- (a) Certified registration required. All facilities with therapeutic radiation machines as defined in and subject to the requirements of this Article must maintain a certified registration for such therapeutic radiation machines from the Department in accordance with the provisions of this section.
- (b) Certified registration application.
  - (1) An application for a certified registration must be made to the Department in a manner prescribed by the Department
  - (2) If the application is for use sited in a medical institution, only a person serving as a principal officer or director on the institution's executive management may apply; for use not sited in a medical institution, a professional practitioner may apply.
  - (3) When a change affecting a radiation source or installation subject to the certified registration requirements of this section is considered by a registrant, including but not limited to changes ordered pursuant to this Article, so that the information on file with the Department will no longer be accurate, then the registrant must so inform the Department in writing:
    - (i) for administrative changes, such as a change in business name, such notification must be made to the Department within 10 days of such change.
    - (ii) for all other changes, an amendment must be requested and received pursuant to this section.
    - (iii) failure to notify the Department of a change of ownership or address of a radiation installation may result in suspension or revocation of the installation's certified registration.
  - (4) At any time after the filing of an application for a certified registration, the Department may require the applicant to submit a supplementary information statement to enable the Department

- to determine whether such application should be approved or denied, or whether a previously issued registration should be amended, suspended or revoked.
- (5) Each application or supplementary information statement must be signed by either the applicant personally or a person duly authorized by the applicant acting as its agent to sign on the applicant's behalf.
- (6) The Department may approve an application for a certified registration if the Department determines that the following requirements have been met:
- (i) the applicant's proposed use, equipment, facilities and procedures can be reasonably expected to protect health and safety and minimize danger to life and property from radiation hazards; and
  - (ii) the applicant's instrumentation is appropriate for detecting and measuring the type of radiation produced (either directly or indirectly) by the radiation source requested in the application; and
  - (iii) the applicant or the applicant's personnel are qualified by licensure, training and experience to use such radiation source for the purposes covered by the application so as to protect health and safety and minimize danger to life and property from radiation hazards; and
  - (iv) the applicant submits sufficient information to support a reasonable determination that the requirements of this Article will be met.
- (7) Certified registrations issued by the Department pursuant to application shall be in the form of a written authorization permitting possession and use of radiation therapy machines. Such possession and use shall be subject to ongoing compliance with all applicable provisions of this Article and all conditions as stated on the certified registration.
- (c) Certified registration; expiration, termination and amendment.
- (1) Except as otherwise provided in this Article, or authorized by the Department, each certified registration shall expire on the expiration date stated on the certified registration. If any current certified registrant duly files with the Department an application in proper form for renewal of such certified registration, or for a new and superseding certified registration, not less than 30 days prior to the stated expiration date, such certified registration shall not be deemed to have expired until the Department has decided such renewal application.
- (2) The Department may terminate any certified registration upon the written request of the registrant.
- (3) The Department may at any time set forth in any certified registration or incorporate by reference therein, additional conditions, restrictions or requirements applicable to the registrant's transfer, receipt, possession or use of any radiation source covered by such certified registration in order to protect the public health and safety and to minimize danger to life and property from radiation hazards.
- (4) Any certified registration may be amended or revoked by the Department by reason of amendment of this Article, or any other applicable law or regulation.
- (5) Any certified registration may be suspended or revoked by the Department for any basis provided in this Article, including but not limited to, the following:
- (i) any material misstatement in the application or in any supplementary statement thereto;
  - (ii) any condition revealed by such application, supplementary statement, report, record, inspection, investigation or other means, which would warrant the Department's refusal to grant a certified registration on an original application; or
  - (iii) any violation or failure to observe any condition of such certified registration, this Article, or any other applicable law, rule, regulation or order now or hereafter in effect.
- (6) A registrant must apply for, and must have received approval for, a certified registration amendment before:
- (i) permitting anyone not listed on the registrant's certified registration to work as an authorized user under the certified registration;
  - (ii) permanently changing the radiation safety officer;

- (iii) making any change in the treatment room shielding;
  - (iv) making any change in the location of the therapeutic radiation machine within the treatment room;
  - (v) using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the treatment room;
  - (vi) relocating the therapeutic radiation machine;
  - (vii) allowing an individual not listed on the registrant's certified registration to perform the duties of the QMP, except during the temporary absence of the QMP when a person who is otherwise qualified to perform such duties may perform such duties; such temporary absence must not exceed 60 days; or
  - (viii) changing non-administrative statements, representations or procedures incorporated by reference into the certified registration.
- (7) Any application by a registrant for an amendment of a certified registration must be filed in writing with the Department and must set forth in detail the reasons for such requested amendment.

**§175.42 Registration of mobile service operations.**

For purposes of this section, mobile service operations means an x-ray unit of any type that is used in a van or similar vehicle to conduct x-ray examinations outside a fixed location. In addition to the requirements of §175.40, the applicant must provide the following information:

- (a) an established main location where the machines, records, etc. will be maintained for inspection. This must be a street address, not a post office box number.
- (b) a sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location; and
- (c) a current copy of the applicant's operating and safety procedures, including radiological practices for protection of patients, operators, employees and the general public.

**§175.43 Assembler or transfer obligation.**

- (a) Any person who sells, leases, transfers, lends, disposes, assembles or installs radiation machines in New York City must notify the Department within 15 days of:
  - (1) the name and address of persons who have received these machines;
  - (2) the manufacturer, model, and serial number of each radiation machine transferred; and
  - (3) the date of transfer of each radiation machine.
- (b) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation meet the requirements of this Article and any other applicable law.
- (c) The submission to the Department of FDA Form 2579 (Report of Assembly of a Diagnostic X-ray System) shall be deemed to meet all the requirements of this section.

**§175.44 Requirements for technical reports.**

- (a) All surveys, audits, reports, or other work ("technical report") performed by a QMP or CRESO as required by this Article must be reviewed and signed by such QMP or CRESO.
- (b) If the Department determines that any technical report of any QMP or CRESO providing services required by this Article are inadequate to assess radiation exposures, the Department may require such technical report to be revised or re-done according to specifications provided by the Department, or if this is not satisfactory, the Department may require the registrant or licensee to have such technical report performed by another QMP or CRESO. If the Department makes such a determination, it shall notify such QMP or CRESO of such determination and allow such QMP or



CRESO an opportunity to be heard before the Department prior to any notification by the Department of its determinations, if any, to such individual's appropriate certifying agency.

**§175.46 Requirements for an operator's booth.**

- (a) Stationary radiographic systems. Stationary radiographic systems must have the x-ray control, including the exposure switch, permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.
- (b) Mobile, portable, podiatric, dental (except CBCT), and mammographic radiographic installations are exempt from the requirements of §175.46(d) through (g), and must meet the requirements in §175.46(h) or (i).
- (c) Dual-energy X-ray absorptiometry (DXA) systems are exempt from the requirements of this section, and must meet the requirements of §175.52.
- (d) Space requirements.
  - (1) The operator must be allotted at least 0.70 m<sup>2</sup> (7.5 square feet) of unobstructed floor space in the booth;
  - (2) The operator's booth may be any geometric configuration with all dimensions at least 0.6 m (2 feet);
  - (3) Paragraphs (1) and (2) of this subdivision only apply to installations constructed after July 1, 2021.
  - (4) The space must not have any obstruction near the x-ray control panel, such as overhang, cables, or other similar obstructions;
  - (5) The booth must be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall-mounted image receptor will not reach the operator's position in the booth.
- (e) Structural requirements.
  - (1) The booth walls must be permanently fixed barriers of at least 2.1 m (7 feet) 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 must be provided to meet the requirements for the occupational radiation exposure requirements of this Article.
- (f) Radiation exposure control placement. The radiation exposure control for the system must be fixed within the booth and:
  - (1) must be at least 1.0 m (40 inches) from any point subject to direct scatter, leakage or primary beam radiation; and,
  - (2) must allow the operator to use the majority of the available viewing windows.
- (g) Viewing system requirements. Each booth must have at least one viewing device which will:
  - (1) be so placed that the operator can view the patient during any exposure; and
  - (2) 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 which allows access to the room cannot be seen from the booth, then outside that door there must be an "x-ray on" warning sign that will be lighted whenever an x-ray exposure is initiated. Alternatively, an interlock must be present such that exposures are prevented when the door is open.
  - (3) When the viewing system is a window, the following requirements also apply:
    - (i) the window must have a viewing area of at least 0.09 m<sup>2</sup> (1 square foot);
    - (ii) regardless of size or shape, at least 0.09 m<sup>2</sup> (1 square foot) of the window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor;
    - (iii) the window must have at least the same lead equivalence as that required in the booth's wall in which it is mounted.
  - (4) When the viewing system is by mirrors, the mirrors must be located to allow the operator to view the patient during any exposure and allow full view of any occupant of, or entry into the room.

- (5) When the viewing system is by electronic means, the camera shall be located to allow the operator to view the patient during any exposure and allow full view of any occupant of, or entry into the room.
- (h) Mobile, portable, podiatric and dental radiographic installations (except CBCT), excluding mammographic systems. (1) Mobile, portable, podiatric and dental x-ray equipment must allow an operator to stand at least 2 m (6.5 ft.) from the patient or behind a protective barrier of at least 2.1 m (7 feet) high, and not in the path of the primary x-ray beam whenever an x-ray exposure is initiated. (2) Mobile and portable x-ray systems, excluding dental and podiatric systems, that are used continuously for greater than one week in the same location shall be deemed a fixed radiographic installation and must meet the operator protection standards for fixed radiographic equipment. (3) Each operator of a mobile or portable radiographic x-ray unit, excluding dental and podiatric units, must be provided with personnel monitoring as provided in §175.17 and must wear a protective garment of at least 0.25 mm lead equivalent.
- (i) Mammographic installations. The operator of the mammographic equipment must initiate x-ray exposures from the control console of the mammographic equipment with protective shielding for the operator that meets the following criteria:
- (1) the shielding must be a height of 2.1 m (7 ft.) from the floor, with the lower edge not more than 7.5 cm (3 in.) from the floor. The shielding must be constructed as a permanent operator shield such that the operator can stand completely within the shielded area during the exposure; and
- (2) the exposure control must be permanently fixed on the mammographic control console; and
- (3) the operator must be able to communicate with and view the patient from the operator's protected position during the exposure.
- (j) Operator protective garments.
- (1) The facility must include a written policy and procedure in the quality assurance manual that conforms to the manufacturer's recommended care and use policy for lead protective garments and is adhered to on a continuing basis. This policy, at a minimum, must describe the training of Licensed Radiologic Technologists (LRTs) on the proper care and usage of protective garments; how storage sites for lead protective garments will be evaluated and maintained; and include procedures for how LRTs report lead protective garment problems to the radiation safety officer.
- (2) All protective garments must be checked annually for defects such as holes (not including pinholes that do not affect the performance of the protective garment), cracks, and tears by using one or more of the following methods: visual investigation, tactile investigation, or x-ray imaging. Protective garments that are used by operators conducting fluoroscopic procedures must be checked using all three methods listed. If a defect is found, the lead protective garment must be removed from service and either replaced or repaired as needed to conform to the manufacturers' specifications.
- (k) Radiation exposure control.
- (1) Exposure initiation. Means must 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 must not be initiated without such an action. In addition, it must 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 must be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, an audible signal to the operator must indicate that the exposure has terminated.
- (l) Operator and ancillary personnel protection for veterinary systems. All stationary, mobile or portable x-ray systems used for veterinary work must be provided with either a 2 meter (6.5 feet) high protective barrier for operator protection during exposures, or must allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly during exposures. Otherwise, in cases where animals are held, the operator and ancillary personnel must be protected by a minimum of 0.25 mm lead equivalent from scatter radiation and 0.5 mm from the useful beam.

**§175.47 General requirements for all radiation equipment.**

- (a) All x-ray equipment must be installed and operated in accordance with the equipment manufacturer's specifications. If the registrant is required to have a QA program pursuant to §175.12(b)(1), and if the manufacturer's specifications are not available, the registrant's QMP or RSO must establish specifications for equipment use and document the specifications in the registrant's QA Manual. If the Department finds that the specifications present unacceptable tolerances, the Department shall require the registrant to utilize new specifications and shall notify the registrant of such in writing.
- (b) All functional x-ray units registered by the Department shall be subject to inspection by Department staff, or by individuals directed by the Department to inspect such units, such as CRESOs.
- (c) Radiation safety requirements. The registrant shall be responsible for directing the operation of the x-ray system under their administrative control and must assure that the requirements of this Article are met in the operation of the x-ray system.
- (d) A current copy of NYC Health Code Article 175 must be maintained and readily accessible by the registrant either in hard copy or electronic format.
- (e) Registrants required to have a QA program pursuant to §175.12(b)(1) must have a written radiation safety program as part of their QA program. The radiation safety program must include, but not be limited to, the following:
  - (1) that the use of ionizing radiation within its purview is performed in accordance with existing laws and regulations.
  - (2) that all persons are protected as required by this Article.
  - (3) that upon discovery of a medical event (as defined in this Article), the registrant must follow the applicable requirements of §175.25 concerning notification to the Department.
- (f) If an x-ray system does not meet the provisions of this Article, then the registrant must correct such non-compliance, or initiate necessary corrective action, within 30 days of such discovery.
- (g) Individuals operating the x-ray systems must meet all licensure, training and experience qualifications required by the Department.
- (h) A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields must be available to provide the necessary radiation protection for all patients and personnel who are involved with x-ray operations.
- (i) The registrant must use auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information.
- (j) Neither the x-ray tube housing nor the collimating device shall be held during an exposure. Exceptions may be allowed for Department-approved devices specifically designed to be hand-held in the area of patient dental exams. The Department shall maintain a list of hand-held dental units that are approved for clinical exams in New York City, or may accept the list of such hand-held dental units as approved by New York State Department of Health, at the Department's discretion.
- (k) The useful x-ray beam must be limited to the area of clinical interest. For x-ray units not utilizing PBL systems for clinical imaging and not using cones or diaphragms for beam restriction, the clinical x-ray field must be less than size of the image receptor on four of four sides of the image receptor. For all digital image receptors, the size of the clinical image must not be digitally manipulated as to render its original dimensions different from the clinical image size when the image is archived.
- (l) Consideration must be given to selecting the appropriate technique and employing available dose reduction methods and technologies across all patient sizes and clinical indications. For registrants utilizing manual selection of technique settings for clinical x-ray exams, this means a technique chart that employs technique settings for thin, average and heavy patient sizes. In the case where children less than 18 years of age are radiographed, the minimal technique setting should correspond to patients of 1-years old, 5-years old and 10-years old for exams most likely to be administered, e.g., AP chest and abdomen exams. In all such cases, the Entrance Skin Exposure (ESE) must be directly or indirectly determined for all clinical techniques set. At a minimum, these technique charts along with ESEs must include:
  - (1) patient's (adult and pediatric, if appropriate) body part and anatomical size;

- (2) technique factors;
  - (3) type of image receptor used;
  - (4) source to image receptor distance used (except for dental intraoral radiography), and
  - (5) position of the grid for the x-ray exam, i.e., the grid is either removed from the x-ray beam or is in the x-ray beam.
- (m) A facility must have a documented procedure in place for verification of patient identity and exam to be performed, including identification of the appropriate body part.
  - (n) The registrant must create and make available to x-ray operators written safety procedures, including instructions for patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator must be able to demonstrate familiarity with these procedures. Patient holding must be restricted to radiographic examinations with the exception that holding of patients shall be prohibited for all fluoroscopic exams and patient CT exams with the exception of hospital emergency rooms and hospital trauma centers.
  - (o) The registrant must restrict the presence of individuals in the x-ray room of the patient being examined to those required or in training for the medical procedure, or the parent or guardian of a patient while the x-ray tube is energized. Other than the patient being examined, the following applies to all individuals in the x-ray room:
    - (1) all persons must be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.25 millimeter lead equivalent material;
    - (2) If the procedure results in secondary or scatter radiation in excess of 0.02 mSv (2 mrem) in any one hour at the position of these persons, they must be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or must be positioned so that the 0.02 mSv (2 mrem) in any one hour limit is met.
  - (p) Individuals must not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a professional 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 the Department.
  - (q) X-ray patient logbook. Each facility must maintain a written or electronic record containing the patient's name, the type of examinations, and the dates the examinations were performed for all radiographic (except dental, podiatric and veterinary exams) and fluoroscopic patient exams. The administration of contrast agents as part of the patient exam must be noted in the patient logbook to state that IV contrast was administered. All adverse effects to injected contrast agents must be reported to the NY State Health Department, as required by law.
  - (r) Sealing x-ray equipment. Sealing of x-ray units must be done only by the Department for x-ray units, of any type, that poses a hazard to the patient or the operator. No x-ray units sealed by the Department shall be put in use for clinical exams without the approval of the Department.
  - (s) Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source must not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means must be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly.
  - (t) Technique indicators.
    - (1) For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure must be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure must be indicated.

- (2) The requirement of paragraph (1) of this subdivision may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors must be visible from the operator's position except in the case of spot films made by the fluoroscopist.
- (3) The accuracy of the technique factors for the x-ray unit (e.g., indicated kilovoltage peak (kVp), timer accuracy) must meet manufacturer specifications. In the absence of a manufacturer specification, the technique factor accuracy must be within  $\pm 10$  percent.

(u) Beam quality.

- (1) The half value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1 of this subdivision. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table 1, linear interpolation or extrapolation may be made. Positive means must be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place. In no case shall an x-ray unit failing to meet the minimum filtration standards in Table 1 conduct clinical patient exams until the x-ray unit is in compliance with Table 1.

**TABLE 1\***

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

<sup>1</sup> Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.  
<sup>2</sup> 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 this section and manufactured before June 10, 2006.  
<sup>3</sup> All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.  
\* Source: 21 CFR §1020.30 (m)

- (2) Measuring compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.
- (v) Battery charge indicator. On battery-powered generators, visual means must be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
- (w) Modification of certified diagnostic x-ray components and systems.
  - (1) Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 must not be modified except with certified components.

- (2) The owner who causes such modification must record the date and the details of the modification in the system records and maintain this information, and the modification of the x-ray system must not result in a failure to comply with this Article.
- (x) Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected must be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication must be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
- (y) Mechanical support of tube head. The tube housing assembly supports must 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.
- (z) Locks. All position locking, holding, and centering devices on x-ray system components and systems must function as intended.
- (aa) Maintaining compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal Performance Standard for Diagnostic X-Ray Systems (21 CFR §1020.30) must be maintained in compliance with applicable requirements of that standard.

**§175.48 Specific requirements for radiographic x-ray equipment.**

The requirements of this section apply to all non-dental registrants using diagnostic x-ray equipment.

- (a) Acceptance testing. Each registrant must have acceptance testing conducted on all radiographic x-ray units with the exception of dental, podiatric, and bone densitometer units, prior to clinical patient exams being conducted with the designated x-ray units. The acceptance testing must be conducted by a QMP and the report must be provided to the registrant. All non-compliance issues noted in this report must be corrected prior to clinical use of the unit. The acceptance testing report must verify the stated manufacturer's tolerances for all machine testing. If manufacturer tolerances are absent, the registrant's QMP must develop tolerances that must be used in subsequent QA testing by the registrant and must be so noted in the quality assurance manual.
- (b) Control and indication of technique factors.
  - (1) Timers. Means must be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
    - (i) Except during serial radiography, the operator must be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure must cause automatic resetting of the timer to its initial setting or to zero. It must not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.
    - (ii) During serial radiography, the operator must be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.
  - (2) Automatic exposure controls. When an automatic exposure control is provided:
    - (i) indication must be made on the control panel when this mode of operation is selected;
    - (ii) when the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation must be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment must be equal to or less than 1/60 second or a time interval required to deliver 5 milliamperes-seconds (mAs), whichever is greater;
    - (iii) either the product of peak x-ray tube potential, current, and exposure time must be limited to not more than 60 kilowatt-seconds (kW) per exposure or the product of x-ray tube current and exposure time must be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time must be limited to not more than 2,000 mAs per exposure; and

- (iv) a visible signal must indicate when an exposure has been terminated at the limits described in subparagraph (iii) of this paragraph, and manual resetting must be required before further automatically timed exposures can be made.
- (c) Reproducibility.
- (1) Coefficient of variation. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma must be no greater than 0.05.
  - (2) Measuring compliance. Determination of compliance must be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, must also have all variable controls for technique factors adjusted to alternate settings and reset to the test setting after each measurement. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.
  - (3) Alternatively, the reproducibility of any technique value may be determined by taking 5 consecutive measurements and utilizing the formula given below:  

$$\text{Reproducibility} = \frac{\text{maximum measured value} - \text{minimum measured value}}{\text{Average of the measured five values}}$$
The calculated reproducibility shall be equal to  $\pm 10$  percent for compliance.
- (d) Linearity. The following requirements apply for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated. In regard to paragraphs (1) through (3) in this subdivision below, measurements can be made in mR instead of mGy.
- (1) Equipment having independent selection of x-ray tube current (mA). The average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings must not differ by more than 0.10 times their sum. This is:  $|X1 - X2| \leq 0.10(X1 + X2)$ ; where X1 and X2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.
  - (2) Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings must not differ by more than 0.10 times their sum. This is:  $|X1 - X2| \leq 0.10(X1 + X2)$ ; where X1 and X2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.
  - (3) Measuring compliance. Determination of compliance will be based on at least 3 exposures, made within 1 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 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer.
- (e) Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems must meet the following requirements:
- (1) Variable x-ray field limitation. A means for stepless adjustment of the size of the x-ray field must be provided. Each dimension of the minimum field size at an SID of 100 cm must be equal to or less than 5 cm.
  - (2) Visual definition.
    - (i) Means for visually defining the perimeter of the x-ray field must be provided. 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 must not exceed 2 percent

- 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.
- (ii) When a light localizer is used to define the x-ray field, it must provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.
  - (iii) The edge of the light field at 100 cm or at the maximum SID, whichever is less, must have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as  $I_1/I_2$ , where  $I_1$  is the illuminance 3 mm from the edge of the light field toward the center of the field; and  $I_2$  is the illuminance 3 mm from the edge of the light field away from the center of the field..
- (f) Field indication and alignment on stationary general purpose x-ray equipment. Except when spot-film devices are in service, stationary general purpose x-ray systems must meet the following requirements, in addition to those prescribed in subdivision (e) of this section:
- (1) Means must 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 2 percent of the SID, and to indicate the SID to within 2 percent;
  - (2) The beam-limiting device must numerically indicate the field size in the plane of the image receptor to which it is adjusted;
  - (3) Indication of field size dimensions and SIDs must be specified in centimeters or inches and must 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 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and
  - (4) Compliance measurements will be made at each SID in common clinical use (such as SIDs of 100, 150, and 200 cm or 36, 40, 48, 72 inches) and with at least one of the commonly used image receptor dimensions (such as nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches), or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.
- (g) Field limitation on x-ray equipment other than general purpose radiographic systems.
- (1) X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID must 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 image receptor to within 2 percent of the SID, or must 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 the edge of the image receptor.
  - (2) Other x-ray systems. Radiographic systems not specifically covered in subdivisions (e) and (f) of this section, and paragraph (1) of this subdivision, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, must be provided with means 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 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means must be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means must 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. These requirements may be met with:
    - (i) A system which performs in accordance with subdivisions (e) and (f) of this section or when alignment means are also provided, may be met with either;



- (ii) 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. Each such device must have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
- (iii) 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 must indicate the image receptor size and SID for which each aperture is designed and must indicate which aperture is in position for use.
- (h) Positive beam limitation (PBL). The requirements of this subdivision apply to radiographic systems which contain PBL and which the registrant has not disabled.
  - (1) Field size. When a PBL system is provided, it must prevent x-ray production when:
    - (i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or
    - (ii) The sum of the length and width differences stated in subparagraph (i) of this paragraph without regard to sign exceeds 4 percent of the SID.
    - (iii) The beam-limiting device is at an SID for which PBL is not designed for sizing.
  - (2) Conditions for PBL. When provided and if the registrant has not disabled it, the PBL system must function as described in subparagraph (i) of paragraph (1) of this subdivision. whenever all the following conditions are met:
    - (i) The image receptor is inserted into a permanently mounted cassette holder;
    - (ii) The image receptor length and width are less than 50 cm;
    - (iii) The x-ray beam axis is within  $\pm 3$  degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within  $\pm 3$  degrees of horizontal and the SID is 90 cm to 205 cm inclusive;
    - (iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within  $\pm 3$  degrees; and
    - (v) Neither tomographic nor stereoscopic radiography is being performed.
  - (3) Measuring compliance. Compliance with the requirements of subparagraph (i) of paragraph (1) of this subdivision shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (2) of this subdivision are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.
  - (4) Operator initiated undersizing. The PBL system must be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm must be equal to or less than 5 cm. Return to PBL function as described in paragraph (1) of this subdivision must occur automatically upon any change of image receptor size or SID.
  - (5) Override of PBL. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key must be required for any override capability that is accessible to the operator. It must not be possible to remove the key while PBL is overridden. Each such key switch or key must be clearly and durably labeled as follows: "For X-Ray Field Limitation System Failure". The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.
  - (6) Disabling of PBL. A facility has the option to permanently functionally disable a PBL system. When this option is chosen, the standards for manual collimation apply.
- (i) Source-skin distance. The minimum source-skin distance must not be less than 30 cm, except intraoral dental equipment regardless of clinical or veterinary use.

- (j) Radiation from capacitor energy storage equipment. Radiation emitted from the x-ray tube must not exceed:
  - (1) an air kerma of 0.26 microGy (vice 0.03 mR exposure) in 1 minute at 5 cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated ; and
  - (2) an air kerma of 0.88 mGy (vice 100 mR exposure) in one hour at 100 cm from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle).
- (k) Tube stands for portable x-ray systems. Except during veterinary field operations where it is impractical to do so, a tube stand or other mechanical support must be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during an exposure.
- (l) Conditions of use.
  - (1) The x-ray image receptor used as recording medium during the x-ray examination must show visual evidence of cut-off (beam delineation) on all four sides of the x-ray image. This applies to all x-ray units using manual collimation and where no positive means are used to contain the x-ray field to the size of the image receptor. The x-ray image receptor can be film or digital image receptors.
  - (2) Personnel monitoring must be required for all persons operating mobile or portable x-ray equipment, except hand-held dental x-ray units.
  - (3) No person shall be regularly employed to hold patients during exposures nor shall such duty be performed by an individual occupationally exposed to radiation in the course of that individual's other duties. When it is necessary to immobilize the patient, mechanical supporting or immobilizing devices should be used. Written safety procedures must provide the selection criteria for the holder and protocol to be followed during the patient holding procedure.
  - (4) If patients must be held by an individual, that individual must be instructed in personal radiation safety and must be protected with appropriate shielding devices such as protective gloves and a protective garment of at least 0.25 mm lead equivalent. No part of the holding individual's body shall be in the useful beam. The exposure of any individual used for holding patients must be monitored.
  - (5) For patients who have not passed the reproductive age, gonadal shielding of not less than 0.5 mm lead equivalent must be used during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
  - (6) Pregnant women and individuals under 18 years of age must not hold patients under any conditions.

**§175.49 Specific requirements for dental facilities.**

- (a) The following specific quality assurance requirements apply to a dental facility:
  - (1) If using a filmless system, maintain and operate PSP and DDR systems according to manufacturer specifications.
  - (2) The registrant must provide initial training and annual evaluations of x-ray operators to include but not limited to: positioning of the x-ray tube, image processing, operator location during x-ray exposure, source to skin distance, radiation protection, appropriate radiographic protocol and applicable regulatory requirements. Records of training and annual evaluations must be maintained for inspection by the Department.
- (b) Warning label.
  - (1) On systems manufactured on or before June 10, 2006, the control panel containing the main power switch must bear the following warning statement, or the warning statement in paragraph (2) of this subdivision, 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."
- (2) On systems manufactured after June 10, 2006, the control panel containing the main power switch must 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, operating instructions and maintenance schedules are observed."
  - (c) Radiation exposure control. Means must 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 must not be initiated without such an action.
  - (d) Exposure control location and operator protection. Except for units designed to be hand-held, the exposure control must allow the operator to be:
    - (1) behind a protective barrier at least 2 meters (6.5 feet) tall, or
    - (2) at least 2 meters (6.5 feet) from the tube housing assembly, outside the path of the useful x-ray beam, while making exposures.
  - (e) Administrative controls.
    - (1) Patient and image receptor holding devices must be used when the techniques permit.
    - (2) Except for units designed to be hand-held, the tube housing and position indicating device (PID) must not be hand-held during an exposure.
  - (f) Hand-held intraoral equipment. In addition to other requirements in this Article, the following applies specifically to hand-held devices:
    - (1) The hand-held x-ray system must be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device.
    - (2) The facility must maintain documentation that each operator has completed training as specified by the manufacturer.
    - (3) The facility must adopt and follow protocols provided by the manufacturer, and approved by the Department, regarding the safe operation of the device.
    - (4) When operating a hand-held intraoral dental radiographic unit, operators must wear a 0.25 mm lead equivalent apron.
    - (5) If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.
    - (6) The registrant must secure the hand-held device from unauthorized removal or use.
  - (g) Beam-on indicators. The x-ray control must provide visual indication whenever x-rays are produced. In addition, for certified x-ray units, a signal audible to the operator must indicate that the exposure has terminated.
  - (h) Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected must be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication must be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
  - (i) Mechanical support of tube head. The tube housing assembly supports must 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.
  - (j) Battery charge indicator. On battery-powered generators, visual means must be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
  - (k) Technique indicators.
    - (1) For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure must be indicated before the exposure begins.
    - (2) The requirement of paragraph (1) of this subdivision may be met by permanent markings on equipment having fixed technique factors.
  - (l) Exposure reproducibility. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma must be no greater than 0.05.

- (m) Timers. Means must be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
- (n) Kilovolt peak. At a minimum, the kVp must be accurate to within 10 percent on variable kVp units and within 20 percent on fixed kVp units.
- (o) X-ray beam alignment.
  - (1) The useful x-ray beam must be limited to the area of clinical interest.
  - (2) Intraoral dental units.
    - (i) X-ray systems designed for use with an intraoral image receptor must be provided with means to limit the source-to-skin distance (SSD) to not less than 18 cm.
    - (ii) The x-ray field at the minimum SSD must be containable in a circle having a diameter of no more than 7 cm.
  - (3) Extraoral, panoramic and cephalometric units. X-ray systems designed for use with extraoral image receptors and when used with an extraoral image receptor, must be provided with means 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 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means must be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means must 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. These requirements may be met with:
    - (i) 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. Each such device must have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
    - (ii) 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 must indicate the image receptor size and SID for which each aperture is designed and must indicate which aperture is in position for use.
- (p) Beam quality. The Half Value Layer (HVL) of the useful beam for a given x-ray tube potential must not be less than the values shown in Table 1 of §175.47(u). If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table 1, linear interpolation or extrapolation may be made.
- (q) Conditions of use.
  - (1) The x-ray system must always be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of paragraph (2) of subdivision (o) of this section.
  - (2) The operator shall position the end of the position indicating device (PID) within 1 cm (0.4 in.) of the skin of the patient, if such device is routinely used in conducting dental radiography.
  - (3) Time-temperature techniques or automatic processing must be used to develop pre-operative diagnostic dental x-ray films. Processing techniques must be consistent with those recommended by the x-ray film manufacturer. Sight developing of dental radiographs is prohibited except for films taken during operative procedures.
  - (4) Dental x-ray exposure technique factors and dental processing conditions must yield entrance skin exposure (ESE) values for the bitewing x-ray projection that are identical to or do not exceed the maximum range of ESE values for dental "D" and "E" speed film designations as published in HHS document #FDA-85-8245 (August 1985) or superseding documents. With respect to maximum ESE values for digital image receptors (are deemed to be either Computed Radiography (CR) or Digital Image Receptors (DR)), digital image receptors shall be deemed to be equivalent to "E" speed film.
- (r) Facilities possessing a Cone Beam Computed Tomography (CBCT) unit.
  - (1) Notwithstanding anything in this Article to the contrary, dental facilities possessing a CBCT unit must develop and maintain a written quality assurance program, including a written QA manual

and a written radiation safety policy and procedures manual for all CBCT dental equipment possessed by the facility.

- (i) For all dental CBCT units, the registrant must establish annual QA testing of x-ray parameters sufficient to maintain patient doses and image quality consistent over time. The annual tests will evaluate, at a minimum, collimation, filtration, patient dose, accuracy and reproducibility of x-ray techniques and the operational status of x-ray safety features.
  - (ii) For all CBCT units, the QA tests must follow the manufacturer's recommended tests and frequency and utilize the manufacturer's QA phantom. The QA test results will be retained for review by the Department for 5 years, the facility must establish QA testing that includes, at a minimum, the manufacturer's recommended QA tests plus the additional QA tests described in subparagraph (iii) of this subdivision.
  - (iii) Semi-annual QA tests to determine image noise, image uniformity, reconstructed image measurement accuracy, high contrast spatial resolution of the CBCT unit.
  - (iv) Dental facilities possessing a CBCT unit must use a medical physicist who is a QMP in performing its QA activities.
- (2) Dental facilities possessing CBCT equipment must annually determine the patient radiation dose (using direct measurement or indirect means to estimate dose) for the most common CBCT scan used at the facility as conducted by a QMP.
- (3) Dental facilities possessing CBCT equipment must conduct annual QA tests to measure reproducibility of imaging parameters (kVp, exposure time and dimensions of the scan beam), reproducibility of exposure per the most common scan and beam filtration (HVL).
- (4) Conditions of operation for the CBCT unit.
- (i) Facilities possessing a CBCT unit must adhere to the requirements of sections §§175.46 and 175.47 regarding the shielding requirements and operator protection for all CBCT units possessed by the dental facility.
  - (ii) All operators of the CBCT must undergo training on the proper operation of the CBCT units and documentation of this training must be retained by the dental facility for review by the Department until after the next scheduled inspection is completed by the Department.
  - (iii) All operators must be able to communicate with and visually observe the patient during the CBCT examination from the operator's protected position.
  - (iv) CBCT patient exams will not be conducted solely for cosmetic purposes with no diagnostic value to the patient.
  - (v) The logbook for CBCT exams must contain all relevant diagnostic examination information, including but not limited to, x-ray technique, scan time, anatomical exam site and reason for examination.

**§175.50 Podiatric radiography.**

- (a) Equipment. Collimating devices capable of restricting the useful beam to the area of clinical interest must be used. The x-ray films or image receptor used as the recording medium during the x-ray examination must show substantial evidence of cut-off (beam delineation). A device must be provided which terminates the exposure after a preset time interval or exposure. The exposure switch must be of the dead-man type and where protective barriers are required must be so arranged that it cannot be operated outside the shielded area.
- (b) Each installation must be arranged so that the operator can stand at least 2 meters (6.5 feet) from the patient, the x-ray tube and the useful beam during exposure. A protective barrier must be provided when the operator cannot stand at least 2 meters (6.5 feet) away from the patient, the x-ray tube and the useful beam during exposures.
- (c) No person shall hold film during the exposure. Only persons required for the radiographic procedure must be in the radiographic room during exposure.

**§175.51 Veterinary radiography, dental and fluoroscopy.**

**(a) Fixed radiographic installations: equipment.**

- (1) Collimating devices capable of restricting the useful beam to the area of clinical interest must be used.
- (2) The x-ray films or image receptor used as the recording medium during the x-ray examination must show substantial evidence of cut-off (beam delineation).
- (3) A device must be provided which terminates the exposure after a preset time interval or exposure. The exposure switch must be of the dead-man type and must be so arranged that it cannot be operated outside a shielded area.

**(b) Portable or mobile radiographic installations: equipment.**

- (1) Collimating devices capable of restricting the useful beam to the area of clinical interest must be used.
- (2) The x-ray film or image receptor used as the recording medium during the x-ray examination must show evidence of cut-off (beam delineation).
- (3) A device must be provided which terminates the exposure after a preset time interval or exposure.
- (4) A dead-man type of exposure switch must be provided with a cord of sufficient length so that the operator can stand at least 2 meters (6.5 feet) from the animal patient, the x-ray tube and out of the useful beam.

**(c) Veterinary dental x-ray units. The requirements of §175.49 (a) through (r) applies to veterinary dental units with the exception of the ESE requirements of §175.49(q)(3). For hand held dental x-ray units, the same conditions of operation and restrictions on hand held x-ray units (as described in §175.47(j)) apply.**

**(d) Fluoroscopic installations: equipment.**

- (1) Equipment must be so constructed that the entire cross-section of the useful beam is always intercepted by a primary protective barrier regardless of the panel-screen distance. For conventional fluoroscopes, this requirement may be assumed to have been met if, when the collimating system is opened to its fullest extent, an unilluminated margin is left on all edges of the fluorescent screen regardless of the position of the screen during use. Equipment with an image receptor must be so constructed that the useful beam cannot exceed the limits of the input phosphor.
- (2) The exposure must automatically terminate when the barrier is removed from the useful beam.
- (3) The fluoroscopic exposure switch must be of the dead-man type.
- (4) Provision must be made to intercept the scattered x-rays from the undersurface of the tabletop and other structures under the table.
- (5) The source-panel or source-tabletop distance must always be at least 30 cm (12 in.) and is recommended to be not less than 38 cm (15 in.).

**(e) Mobile fluoroscopic equipment must meet the following additional requirements:**

- (1) In the absence of a tabletop, a cone or spacer frame must limit the source-to-skin distance to not less than 30 cm (12 in.).
- (2) Image intensification must always be provided.
- (3) It must not be possible to operate a machine unless the useful beam is intercepted by the image receptor.

**(f) Conditions for operation of equipment.**

- (1) Only persons required for the x-ray procedure shall be in the x-ray room during exposures.
- (2) When an animal patient must be held in position during exposures, mechanical supporting or restraining devices must be used.
- (3) Animal patients or films or image receptors must be held by an individual only under extreme conditions when clinically necessary. Such individuals must wear protective gloves having at least 0.25 mm lead equivalent, a protective garment of at least 0.25 mm lead equivalent, and must keep all parts of their body out of the useful beam.
- (4) The exposure of any individual used for holding animals must be monitored.

- (5) Pregnant women and individuals under 18 years of age must not hold animal patients or films or image receptors under any conditions.
- (6) Protective garments of at least 0.25 mm lead equivalent must be available and must be worn by the fluoroscopist during every fluoroscopy examination.

**§175.52 Dual-energy X-ray Absorptiometry (DXA) (Bone Densitometry).**

- (a) Dual-energy X-ray Absorptiometry (DXA) systems must be:
  - (1) certified by the manufacturer pursuant to the Medical Device Act and Subchapter C – Electronic Product Radiation Control of Chapter V of the Federal Food, Drug and Cosmetic Act;
  - (2) registered in accordance with this Article; and
  - (3) at a minimum, maintained and operated in accordance with the manufacturer’s specifications.
- (b) Operator requirements. Operators of the bone densitometer must either be a professional practitioner or a Licensed Radiologic Technologist. Operators must complete training specific to patient positioning and the operation of the DXA system.
- (c) During the operation of any DXA system, in the absence of a survey performed by or under the supervision of a QMP determining the minimum distance the operator may be from the patient and radiation source, the operator, ancillary personnel, and members of the general public must be positioned at least 2 meters from the patient and DXA system during the examination.
- (d) Quality assurance. The facility must follow the manufacturer’s quality assurance specifications as to required quality control tests, including their frequency.

**§175.53 Fluoroscopic equipment.**

Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy.

- (a) Acceptance testing of fluoroscopic x-ray units. Acceptance testing of fluoroscopic x-ray units must include all quality assurance tests that are mandated to be done at any frequency (for example, all daily, monthly, and annually required tests, etc.) as per the manufacturer’s specifications, or as required by this Article. Each registrant must have acceptance testing conducted on x-ray units with the exception of fluoroscopic mini c-arms of II sizes less than 6 inches prior to clinical patient exams being conducted with the designated x-ray units. The acceptance testing must be conducted by a QMP and the report provided to the registrant. All non-compliance issues noted in this report must be corrected prior to clinical use of the unit. The acceptance testing report must verify the stated manufacturer’s tolerances for all machine testing. If manufacturer tolerances are absent, the QMP must develop tolerances that must be used in subsequent quality assurance testing by the registrant and must be so noted in the facility’s quality assurance manual.
- (b) Primary protective barrier.
  - (1) Limitation of useful beam. The fluoroscopic imaging assembly must be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy must not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor must not exceed  $3.34 \times 10^{-3}$  percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems are exempt from this requirement provided the systems are intended only for remote control operation.
  - (2) Measuring compliance. The AKR must be measured in accordance with subdivision (i) of this section. If the source is below the tabletop, the measurement must be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement must 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 is not closer than 30 cm. Movable grids and compression devices must be removed from the useful beam during the measurement. For all measurements, the attenuation block must be positioned in the

useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

(c) Field limitation.

(1) Angulation. For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with subdivisions (e) and (f) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(2) Further means for limitation. Means must be provided to permit further limitation of the x-ray field to sizes smaller than the limits of subdivisions (e) and (f) of this section. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or capability of a visible area of greater than 300 cm<sup>2</sup>, must be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 cm<sup>2</sup> must be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 cm<sup>2</sup> or less. Stepless adjustment must, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm.

(3) Spot-film devices. In addition to the applicable requirements of §§175.47 and 175.48, the following requirements also apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(i) Means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment must be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size must not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(ii) Neither the length nor 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 percent 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 must not exceed 4 percent of the SID. 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 must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(iii) The center of the x-ray field in the plane of the image receptor must be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

(iv) Means must be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(A) for spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

(B) for spot-film devices used on fluoroscopic systems that have a variable SID or stepless adjustment of the field size, the minimum field size, at the greatest SID, must be containable in a square of 5 cm by 5 cm.

(d) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position must indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch must be clearly labeled as follows: "For X-ray Field Limitation System Failure".



- (e) Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.
- (1) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:
    - (i) Neither the length nor 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 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
    - (ii) 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.
  - (2) 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 must conform with one of the following requirements:
    - (i) 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, 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 1.5 cm, or
    - (ii) 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 2 cm.
- (f) Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors. For x-ray systems manufactured on or after June 10, 2006, the following applies:
- (1) Neither the length nor 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 percent of the SID. The sum of the excess length and the excess width must be no greater than 4 percent of the SID.
  - (2) 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.
- (g) Override capability. If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position must indicate whenever the automatic field adjustment is overridden. Each such system failure override switch must be clearly labeled as follows: "For X-Ray Field Limitation System Failure".
- (h) Activation of tube. X-ray production in the fluoroscopic mode must be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, the operator must be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.
- (i) Air kerma rates. For fluoroscopic equipment, the following requirements apply:
- (1) Fluoroscopic equipment manufactured before May 19, 1995.
    - (i) Equipment provided with automatic exposure rate control (AERC) must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in subdivision (m), except as specified in paragraph (2) of subdivision (m) of this section.
    - (ii) Equipment provided without AERC must not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in paragraph (2) of subdivision (m), except during recording of fluoroscopic images.
    - (iii) Equipment provided with both an AERC mode and a manual mode must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy

- per minute (vice 10 R/min exposure rate) in either mode at the measurement point specified in paragraph (2) of subdivision (m), except during recording of fluoroscopic images.
- (iv) Equipment may be modified in accordance with this Article to comply with paragraph (2) of this subdivision. When the equipment is modified, it must bear a label indicating the date of the modification.
- (2) Fluoroscopic equipment manufactured after May 19, 1995:
- (i) must be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in paragraph (2) of subdivision (m) of this section Provision for manual selection of technique factors may be provided.
- (ii) must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in paragraph (2) of subdivision (m) of this section, except as specified in in paragraph (3) of this subdivision.
- (3) Exceptions.
- (i) 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.
- (ii) 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 after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.
- (j) Fluoroscopy equipment with optional high-level control. When high-level control is selected and the control is activated, in which case the equipment must not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (vice 20 R/min exposure rate) at the measurement point specified in paragraph (2) of subdivision (m) of this section. Special means of activation of high-level controls shall be required. The high-level control must 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.
- (k) With the system configured in the non-mag mode of operation for the most frequently performed fluoroscopic procedure including the grid orientation in or out and the dose adjustment selection set the same as the most common exam, the exposure rates must be measured with each of the following attenuators in the beam:
- (1) 0.75 inches (19 mm) of aluminum (pediatric patient),
- (2) 1.50 inches (38 mm) of aluminum (small adult patient),
- (3) 1.50 inches (38 mm) of aluminum and 0.02 inches (0.5 mm) of copper (average adult patient),
- (4) 1.50 inches (38 mm) of aluminum and 0.08 inches (2.0 mm) of copper (large adult patient),
- (5) 1.50 inches (38 mm) of aluminum and 0.08 inches (2.0 mm) of copper and 0.12 inches (3.0 mm) of lead (for maximum fluoroscopic exposure rate only).
- This report of fluoroscopic exposure rates for the most frequently performed procedure must be posted so that they are conspicuous to the operator.
- (l) For all fluoroscopic x-ray systems having an Automatic Brightness system, for phantom measurements conducted in subdivision (k) paragraphs (1) through (4), simulating clinical conditions, the automatic brightness system must function according to manufacturer's specifications as to adjusting the fluoroscopic techniques of kVp and/or mA. If manufacturer's specifications are not available, the specifications must be present in the facility's QA manual. In all cases for measurements required by paragraphs (2) through (4) in subdivision (k), there must be a continuous increase in the fluoroscopic exposure rate for each step from the previous step.
- (m) Entrance exposure rate limits.
- (1) The fluoroscopic exposure rate when measured under the following conditions should not exceed 3 Roentgens per minute and must not exceed 5 Roentgens per minute:

- (i) the controls are set to the dose rate mode used for the fluoroscopic procedure most commonly performed on that fluoroscopic unit; and
  - (ii) the image receptor is set to the largest field of view; and
  - (iii) the image receptor is at 12 inches (30 cm) above the tabletop or the over table fluoro tube is at a source to image distance normally used for an average patient; and
  - (iv) a patient phantom composed of 1 and 1/2 inch (3.8 cm) thickness of Type 1100 aluminum and 0.02 inch (0.5 mm) thickness of copper or an equivalent device is completely intercepting the useful beam.
- (2) Measuring compliance. Compliance with paragraph (1) of subdivision (m) of this section shall be determined as follows:
- (i) If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop or cradle.
  - (ii) If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
  - (iii) In a C-arm type of fluoroscope, the AKR shall be measured at 30 cm 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 cm from the input surface of the fluoroscopic imaging assembly.
  - (iv) In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.
  - (v) In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm 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 cm to the centerline of the x-ray table.
- (3) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements in this subdivision when used for therapy simulation purposes.
- (n) Resolution tests.
- (1) The spatial resolution of the fluoroscopic system must be measured using a test tool composed of a line pair (lp) plate with discreet line pair groups and a maximum lead foil thickness of 0.1 mm or an equivalent device. The test tool must be placed on a 0.75 inch (19 mm) thickness of type 1100 aluminum, large enough to completely intercept the useful beam, with the test tool 12 inches (30 cm) from the entrance surface of the image receptor assembly. If the system has variable source-to-image distance (SID), the measurement SID must not exceed 40 inches (100 cm). The image receptor of the fluoroscopic system must be operated in the 6 inches (15 cm) field of view (FOV) to conduct this test. If 6 inches (15 cm) FOV is not available, the system must be operated in the smallest FOV that exceeds the 6 inches (15 cm) FOV. The minimum spatial resolution at the center of the beam for all FOVs shall be determined by the following equation:  $2 \text{ lp/mm} \times (6 \text{ inches (15cm)}/\text{size of FOV used}) = \text{minimum number of lp/mm}$ .
  - (2) The low contrast performance of the fluoroscopic system must be capable of resolving a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and a phantom composed of a 1 and 1/2 inch (3.8 cm) thickness of Type 1100 aluminum large enough to completely intercept the useful beam or an equivalent device. The test tool must be 12 inches (30 cm) from the entrance surface of the image receptor assembly. The image receptor of the fluoroscopic system must be operated in the 6 inches (15 cm) FOV to conduct this test. If 6 inches (15 cm) FOV is not available, the system must be operated in the smallest FOV that exceeds the 6 inches (15 cm) FOV.

- (3) Exemptions. For all fluoroscopic systems with an image receptor diameter of less than 6 inches, or labeled and clinically used for extremity only, the high and low contrast tests need not be conducted.
- (o) Indication of potential and current. During fluoroscopy and cinefluorography, x-ray tube potential and current must be continuously indicated. Deviation of x-ray tube potential and current from the indicated value must not exceed the maximum deviation as stated by the manufacturer.
- (p) Source-skin distance.
- (1) Means must 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 or interventional applications that would be impractical at the source-skin distances specified in this paragraph, 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 must be provided to limit the source-skin distance to not less than 19 cm. Such systems must be labeled for extremity use only. In addition, for those systems intended for specific surgical or interventional applications that would be impractical at the source-skin distance specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.
- (q) Fluoroscopic irradiation time, display, and signal.
- (1) Fluoroscopic equipment manufactured before June 10, 2006:
- (i) Must be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device must not exceed 5 minutes without resetting. A signal audible to the fluoroscopist must indicate the completion of any preset cumulative irradiation time. Such signal must continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR §1020.30(q) to comply with the requirements of this paragraph.
- (ii) As an alternative to the requirements of this paragraph, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.
- (2) For x-ray controls manufactured on or after June 10, 2006, there must be provided for each fluoroscopic tube a display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display must function independently of the audible signal described in this subsection. The following requirements apply:
- (i) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes must be continuously displayed and updated at least once every 6 seconds.
- (ii) The fluoroscopic irradiation time must also be displayed within 6 seconds of termination of an exposure and remain displayed until reset.
- (iii) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure. A signal audible to the fluoroscopist must sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure. The signal must sound until manually reset or, if automatically reset, for at least 2 seconds.
- (r) Display of last-image-hold (LIH).
- (1) Fluoroscopic equipment manufactured on or after June 10, 2006, must be equipped with means to display LIH image following termination of the fluoroscopic exposure.
- (i) For an LIH image obtained by retaining pre-termination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection must be indicated prior to initiation of the fluoroscopic exposure.
- (ii) For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image must be

- selectable prior to the fluoroscopic exposure, and the combination selected must be indicated prior to initiation of the fluoroscopic exposure.
- (iii) Means must be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph must be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.
- (s) Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, must display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:
- (1) When the x-ray tube is activated and the number of images produced per unit time is greater than 6 images per second, the AKR in mGy/min must be continuously displayed and continually updated.
- (2) The cumulative air kerma in units of mGy must be displayed either within 5 seconds of termination of an exposure or displayed continuously and regularly updated.
- (3) The display of the AKR must be clearly distinguishable from the display of the cumulative air kerma.
- (4) The AKR and cumulative air kerma must represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.
- (i) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location must be the respective locations specified in subparagraphs (i), (ii) or (v) of paragraph (2) of subdivision (m) of this section.
- (ii) For C-arm fluoroscopes, the reference location must be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location must be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.
- (iii) Means must be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.
- (iv) The displayed AKR and cumulative air kerma must not deviate from the actual values by more than  $\pm 35$  percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.
- (t) Protection from scatter radiation.
- (1) For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, must be available and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.
- (2) Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions must be met:
- (i) shielding required under paragraph (1) of this subdivision must be maintained to the degree possible under the clinical conditions.
- (ii) all persons, except the patient, in the room where fluoroscopy is performed must wear protective aprons that provide a lead equivalent shielding of at least 0.25 mm, except if such persons are protected by movable lead shields of 0.25 mm lead equivalent.
- (iii) Operating and safety procedures must reflect the above conditions, and fluoroscopy personnel must exhibit awareness of situations requiring the use or non-use of the protective drapes.
- (u) Operator qualifications.
- (1) In addition to the applicable requirements of this Article, the operation of a fluoroscopic x-ray system for clinical purposes must be limited to:
- (i) a licensed practitioner working within his or her scope of practice; and

- (ii) a medical resident or radiologic technology student, in training, and only under the direct personal supervision of the licensed practitioner meeting the conditions of subparagraph (i) of this paragraph (1).
- (2) All persons operating, or supervising the operation of, fluoroscopy systems for clinical use must have completed appropriate training. Effective July 1, 2021, the registrant must ensure that prior to performing fluoroscopy procedures, each person operating, or supervising the operation of, fluoroscopy systems completed the training required in this paragraph. The training topics must include:
  - (i) basic properties of radiation;
  - (ii) biological effects of x-ray;
  - (iii) radiation protection methods for patients and staff;
  - (iv) units of measurement and dose, including DAP (dose-area product) values & air kerma;
  - (v) factors affecting fluoroscopic outputs;
  - (vi) high level control options;
  - (vii) dose management including dose reduction techniques, monitoring, and recording;
  - (viii) principles and operation of the specific fluoroscopic x-ray system to be used;
  - (ix) fluoroscopic and fluorographic outputs of each mode of operation on the system to be used clinically; and
  - (x) all applicable requirements of this Article.
- (3) All persons operating, or supervising the operation of, fluoroscopy systems during clinical FGI procedures must have completed a minimum of 8 hours of training. Effective July 1, 2021, the registrant must ensure that prior to performing fluoroscopy procedures each person operating, or supervising the operation of, fluoroscopy systems completed the training required in this paragraph. The topics must include:
  - (i) the topics provided in 175.53(u)(2);
  - (ii) methods to reduce patient dose using advanced imaging and recording features;
  - (iii) procedures for recording pertinent data specified in subdivision (x) of this section.
  - (iv) a minimum of one hour of hands-on fluoroscopic machine training demonstrating application of topics required in this subdivision.
- (4) The training required by paragraph (3) of this subdivision must be provided by a QMP or another individual approved by the Department.
- (5) The registrant must either provide a minimum of 2 hours in-service training every 2 years for all individuals operating or supervising the operation of fluoroscopy systems during clinical FGI procedures, or require evidence of continuing medical education meeting the conditions of this subdivision.
- (6) Documentation pertaining to the requirements of this section must be maintained for review for 5 years.
- (v) Equipment operation.
  - (1) All fluoroscopic images must be viewed, directly or indirectly, and interpreted by a professional practitioner of the healing arts.
  - (2) Overhead fluoroscopy must not be used as a positioning tool for general purpose radiographic examinations.
  - (3) Operators must be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features, and the relative radiation output rates of the various modes of operation.
  - (4) Procedure planning for fluoroscopic procedures on pregnant patients must include feasible modifications to minimize the dose to the conceptus.
  - (5) The facility must establish a written policy regarding patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 – 2013), NCRP Report 168, or successor or equivalent standard.

- (6) Fluoroscopic systems that fail to comply with subdivisions (l) and (n) of this section must not be used for patient fluoroscopy. The failure shall be determined by the QMP report to the facility conducted as part of the facility's routine QA program testing and non-compliance with Article 175 requirements so noted in the QMPs' reports.
- (w) Additional requirements for facilities performing fluoroscopically-guided interventional (FGI) procedures.
- (1) A registrant utilizing FGI procedures must establish a Radiation Protocol Committee (RPC) in accordance with the following:
- (i) the registrant may establish a system-wide committee if the registrant has more than one site.
  - (ii) if the registrant has already established a radiation safety committee, the requirements of this subsection may be delegated to that committee if the members meet the requirements of paragraph (5) of this subdivision.
- (2) A quorum of the RPC must meet as often as necessary, but at intervals not to exceed 12 months.
- (3) Record of RPC. A record of each RPC meeting must include the date, names of individuals in attendance, minutes of the meeting, and any actions taken. The registrant must maintain the record for inspection by the Department.
- (4) Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee.
- (5) RPC Members. Members must include but not be limited to the following individuals:
- (i) a supervising physician of the healing arts who meets the requirements in subdivision (u) of this section;
  - (ii) a QMP;
  - (iii) the lead technologist or a senior technologist; and
  - (iv) other individuals as deemed necessary by the registrant.
- (6) Establish and implement FGI procedure protocols.
- (i) The RPC must establish and implement written protocols, or protocols documented in an electronic report system, that include but are not limited to the following:
    - (A) identification of individuals who are authorized to use fluoroscopic systems for interventional purposes.
    - (B) a method to be used to monitor patient radiation dose during FGI.
    - (C) SRDL values following nationally recognized standards.
    - (D) actions to be taken for cases when a SRDL is exceeded which may include patient follow-up.
    - (E) a review of the established protocols at an interval not to exceed 12 months.
  - (ii) A record of each RPC protocol must be maintained for inspection by the Department. If the RPC revises a protocol, documentation must be maintained that includes the justification for the revision and the previous protocol for inspection by the Department.
- (7) Procedures for maintaining records.
- (i) A record of radiation output information must be maintained so the radiation dose to the skin may be estimated in accordance with established protocols. The dose estimation methodology must be in written document and available for review during periodic department inspections. The record must include the following:
    - (A) patient identification;
    - (B) type and date of examination;
    - (C) identification of the fluoroscopic system used; and
    - (D) peak skin dose, cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.
    - (E) if the peak skin dose, cumulative air kerma or dose area product are not displayed on the fluoroscopic system, records must include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following as necessary:
      - a. fluoroscopic mode, such as, high-level or pulsed mode of operation;

- b. cumulative fluoroscopic exposure time; and
- c. number of films or recorded exposures.
- (ii) The registrant must maintain records required by this subparagraph for inspection by the Department for 5 years.

**§175.54 Mammography and breast stereotactic x-ray.**

- (a) Applicability. The requirements of this section apply to all facilities which produce, process or interpret mammograms, including breast tomosynthesis, for screening or diagnostic purposes (“mammography facility”) and are in addition to, and not in substitution for, other requirements of this Article.
- (b) Requirement for certification.
  - (1) Except for facilities holding provisional certificates as described in paragraph (2) of this subdivision, each mammography facility must have received a certificate indicating approval by the U.S. Food and Drug Administration (FDA) to provide screening and diagnostic mammography services pursuant to 21 CFR §900.11, or any successor law or regulation.
  - (2) A provisional certificate issued pursuant to 21 CFR §900.11, or any successor law or regulation, will be accepted in lieu of the certificate required by paragraph (1) of this subdivision for a period of no longer than 6 months from the date of issuance plus one 90 day extension.
- (c) Revocation of accreditation and accrediting body approval.
  - (1) If a facility's accreditation is revoked by an accrediting body (as defined in 21 CFR §900.2), the facility's certificate (as defined in 21 CFR §900.2) shall remain in effect until such time as determined by the FDA or other certifying body on a case-by-case basis after an investigation into the reasons for the revocation. If the FDA or other certifying body determines that the revocation was justified by violations of applicable quality standards, the FDA or other certifying body will suspend or revoke the facility's certificate or require the submission and implementation of a corrective action plan, whichever action will protect the public health in the least burdensome way.
  - (2) If the approval of an accrediting body is revoked by FDA, the certificates of the facilities accredited by such body shall remain in effect for a period of ) year after the date of such revocation subject to FDA's determination that the facility is continuing to perform mammography of acceptable quality. The facility must obtain accreditation from an approved accrediting body within 1 year of the date of revocation.
- (d) Breast stereotactic x-ray. Breast stereotactic x-ray units dedicated to breast biopsy procedures are exempt from subdivisions (b) and (c) of this section. Each facility must at a minimum follow testing guidelines recommended by the American College of Radiology (ACR), or follow manufacturer recommended testing at the frequency specified. At least annually, each facility must have a QMP conduct an annual assessment of each breast stereotactic x-ray unit. The latter assessment must be in the form of a report submitted to the facility and all reported non-compliance items must be corrected within 30 days.

**§175.55 Computed tomography (CT) equipment.**

Except for dental registrants possessing cone beam computed tomography, each facility utilizing computed tomography equipment must comply with the requirements of this section.

- (a) CT x-ray system equipment requirements.
  - (1) Each control panel and gantry of a CT x-ray system must include visual signals that indicate to the operator of the CT x-ray system whenever x-rays are being produced and when x-ray production is terminated, and, if applicable, whether the shutter is open or closed.
  - (2) Each CT x-ray system must be equipped with a control that allows the operator of the CT x-ray system to terminate the x-ray exposure at any time during a scan, or series of scans, when the exposure time is greater than one-half second duration.



- (3) Each CT x-ray system must 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.
- (4) Each CT x-ray system must include a clearly and conspicuously labeled emergency shutoff button or switch.
- (5) Premature termination of the x-ray exposure by the operator must require resetting of the CT conditions of operation by the operator prior to the initiation of another scan.
- (b) Patient communication and viewing requirements.
  - (1) Each CT x-ray system must be equipped to allow two-way aural communication between the patient and the operator at the control panel.
  - (2) Each CT x-ray system must be equipped with windows, mirrors, closed-circuit television, or an equivalent to permit continuous visual observation of the patient during CT scanning by the CT operator from the control panel.
  - (3) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) must be available for if the primary viewing system fails.
- (c) Determination of the CT unit radiation output.
  - (1) Each registrant must ensure that the measurement of the radiation output of each CT x-ray system that it operates is performed by, or under the direction of, a QMP and the output measurement must be conducted following the guidelines of the facility's accreditation as to methodology and as to setting scan techniques and CT unit technique settings.
  - (2) Each registrant must maintain and make available for review by the Department, on the premises of its radiation installation where a CT x-ray system is located, written procedures for the appropriate output measurement of the CT x-ray system.
  - (3) After initial installation, the CT x-ray system radiation output must be determined prior to its use on human beings and re-measured at least every 12 months thereafter. Any change or replacement of components of a CT x-ray system which could cause a change in the radiation output will require a re-measurement within 30 days of component installation under the supervision of a QMP operating within their scope of practice. If the accreditation body does not dictate the criteria for re-measurement based upon CT component replacement, then the facility must establish these criteria in conjunction with the QMP and CT service engineer, including the list of components that dictate a re-measurement, and this protocol must be documented in the facility's QA Manual.
  - (4) The measurement of the radiation output of a CT x-ray system must be performed with a calibrated dosimetry system. This system must have been calibrated either by the National Institute of Standards and Technology (NIST) or traceable to NIST or equivalent standards organization. The calibration must have been performed within the previous 12 months and after any servicing that might have affected system calibration.
  - (5) The CT dosimetry phantoms must meet the following specifications and conditions of use:
    - (i) any effects on the doses measured because of the removal of phantom material to accommodate dosimeters must 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; and
    - (ii) all dose measurements must be performed with the CT dosimetry phantom simulating an adult abdomen or adult head placed on the patient couch or support device without additional attenuation materials present.
    - (iii) the requirements of subparagraphs (i) and (ii) of this paragraph can also be met by using an alternative method of radiation measurement and calculation published in the peer-reviewed scientific literature and acceptable to the Department.
  - (6) Records of radiation output determinations performed must be maintained for 3 years at the radiation installation where the CT is located.
- (d) Quality assurance testing.
  - (1) Each registrant possessing one or more CT units shall be deemed a large facility.

- (2) Regardless of the number of patient exams conducted per year all Quality Assurance (QA) tests for existing x-ray equipment on site must be done on a frequency for a large facility. As such, each registrant must have a QA committee that meets at least semi-annually and such committee must be comprised of the medical professionals associated with the registrant's facility, including the QMP or a representative conducting the accreditation for the facility, the Radiation Safety Officer for the facility, and whatever additional facility titles that the accreditation body mandates to be present for such meetings.
- (3) Each registrant must maintain a QA manual that contains written procedures for all testing and meet the requirements of the facility's accreditation body for maintaining a QA program as to what QA must be done and their mandated testing frequency. The CT Quality Assurance procedures must have been developed under the direction of a QMP and radiologist and be approved by the registrant's QA committee.
- (4) The QA procedures must incorporate the use of one or more phantoms approved by the facility's accreditation body and must be imaged according to the accreditation body's recommendations. If the accreditation body does not provides tolerances for daily CT QA tests, then the facility must follow the manufacturer's specifications for daily CT QA tests and utilization of the manufacturer's phantom for such daily testing. The QA testing of the phantom must have the capability of providing an indication of contrast scale, noise, the resolution capability of the system for low and high contrast objects, and measuring the mean CT Number for water or other reference material and uniformity. All of the aforementioned image quality parameters must be evaluated at least semi-annually by a QMP and presented to the QA Committee for their review and approval.
- (5) Written records of the QA checks performed by the registrant must be maintained for review by the Department for at least 5 years.
- (6) QA checks must include the following:
  - (i) images obtained from x-ray scanning of the CT phantom pursuant to §175.55(d)(4) must be retained as electronic copies stored within the CT x-ray system or stored in the facility's Picture Archiving and Communication (PACS) system, if these images are available based on the CT system.
  - (ii) dose assessment for the most common CT examinations that are performed on the system for which reference levels have been published by the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM) or the National Council on Radiation Protection and Measurements (NCRP) for pediatric head, pediatric abdomen, adult head and adult abdomen.
  - (iii) for brain perfusion studies clinically conducted at the registrant's facility, the registrant must have on an annual basis the clinical dose measured by a QMP and an annual evaluation and approval of the clinical protocols for such brain perfusion studies by the registrant's Radiation Protocol Committee (RPC), or Radiation Safety Committee (RSC), if the RSC assumes the responsibilities of the RPC. The facility must investigate and document the clinical necessity of brain perfusion CTDIvol doses greater than 100 rads (1 Gray) or whatever guidance dose is so stated in the ACR-ASNR-SPR Practice Parameters for the Performance of CT Perfusion in Neurological Imaging (Amended 2014) or superseding documents.
  - (iv) for each CT unit possessing dose adjustment software features for dose adjustment in clinical patient scans:
    - (A) the facility must conduct measurements to determine that the dose adjustment software is functioning as the manufacturer specified to adjust the CT imaging techniques so as to maintain image quality.
    - (B) this must be conducted at least annually or whenever there is a software upgrade or change to the dose adjustment software of the CT software.

- (C) for verification testing as required by clause (A) of this subparagraph (iv) of paragraph (6) of this subdivision, manufacturer test results with documentation and formal report shall be acceptable to verify compliance.
- (7) For CT units used for treatment planning simulation, the registrant must conduct the following QA testing, in addition to daily QA tests mandated by the accreditation agency, if the site is accredited:
- (i) daily measurements to verify that image reconstruction dimensions or scaling accuracy are accurate to manufacturer's tolerances.
  - (ii) daily verification of the CT number uniformity for the manufacturer's water phantom and verify compliance with the manufacturer's tolerances. In this context, CT number uniformity must be conducted for the four quadrants of the water phantom image and compliance shall be determined by comparison between the outer four quadrants and the center of the water phantom as per manufacturer's tolerances.
  - (iii) measure each month the CT number uniformity for a variety of materials with densities above and below that of water and verify compliance with the accreditation body standards or manufacturer specifications.
  - (iv) the registrant can follow the accreditation body's guidelines for the conduct of such measurements and tolerances for such, but the frequency of conduct must be as stated in subparagraphs (i) through (iii) of this paragraph.
- (e) Operating procedures and policies.
- (1) All diagnostic CT and CBCT units for human use must be accredited by an accrediting organization recognized by the Department. This requirement does not apply to CBCT units used at dental facilities and to CT units used solely for simulation of patients for radiation therapy.
    - (i) Effective January 1, 2021, new registrants must be accredited but must demonstrate that they have initiated the accreditation process within 90 days of the start of operations.
    - (ii) Registrants, possessing CT units that have been notified by accrediting agencies that their CT units do not meet minimum standards to be accredited, must notify the Department within 30 days of such notice.
    - (iii) A facility performing CT that has an existing accreditation revoked, repealed, or otherwise terminated for any reason, must report such occurrence to the Department within 30 days.
  - (2) The CT x-ray system must not be operated on a human being except by a physician or by a licensed radiologic technologist who has been specifically trained in the operation of the CT system. To meet compliance with this section, each facility must maintain documentation that each physician or LRT operator of the facility's CT units have received training on the specific manufacturer model that the facility possesses.
  - (3) The registrant must ensure that each CT x-ray system has a radiation protection survey for assessment of exposure to persons in controlled and non-controlled areas made at the time of installation. Any change in the installation that compromises the original integrity of the facility's shielding and installation of a new CT unit shall require an additional radiation protection survey to verify compliance with Article standards for radiation protection doses to the public and radiation workers.
  - (4) Each CT x-ray system must have available at the control panel the operation and output determination of the CT x-ray system which must include:
    - (i) dates of the latest output determination and QA checks and the location within the facility where the results of those tests may be obtained;
    - (ii) instructions on the use of the CT image quality phantoms including a schedule of QA tests that are appropriate for the system as determined by the manufacturer, allowable variations for the indicated parameters.
  - (5) For each CT scanner in a facility, a current set of default protocols are available at the control panel (either electronically or as a document) which specifies for each routine examination the CT conditions of operation and the slice thickness, spacing between slices or pitch. The default

protocols need not be the same as the clinically used scan protocols at the facility, but the clinically used protocols must be derived from the default protocols.

- (6) If the QA testing on the CT x-ray system identifies that a system operating parameter has exceeded a tolerance as specified in the Quality Assurance manual, use of the CT x-ray system on patients must be limited to those exceptions permitted by established written instructions of the licensed QMP or radiologist. Upon completion of corrective action, the QA testing must be repeated to verify that the system is back within tolerance.
  - (7) All clinical CT scans must be free of any and all imaging artifacts that the CT facility discovers upon daily QA phantom testing. Upon discovery of any and all imaging artifacts by way of daily QA phantoms testing, the facility must cease clinical scans until corrective action has removed such artifacts being present in clinical scans, exception for all patient CT scans conducted on emergency cases such as in hospital emergency rooms or hospital trauma centers. All corrective actions must be documented by the registrant for review by the Department.
  - (8) Effective July 1, 2020, each registrant performing CT scans on human beings must ensure that for each scan, the radiation dose delivered by the scanner to a reference phantom or the dose received by the patient or other dose metric is saved and recorded. The dose delivered must be recorded as Computed Tomography Dose Index volume (CTDIvol), dose length product (DLP) or other dosimetry metric published in the peer reviewed scientific literature and acceptable to the Department.
  - (9) The displayed dose must be verified on an annual basis by or under the supervision of a QMP to ensure that the equipment manufacturer's displayed dose is within 20percent of the measured dose. To accomplish the latter, a phantom must be used for this measurement.
  - (10) Each registrant that performs CT scans on human beings must establish and implement a policy and a procedure to ensure that a request for a CT scan originates from a licensed physician or other authorized professional practitioner familiar with the patient's clinical condition. The request must include sufficient information to demonstrate the medical indication for the CT examination and allow for the proper performance and interpretation of the CT scan.
  - (11) Each facility must maintain a patient logbook of all patients undergoing CT exams at the facility. The logbook must contain the following information:
    - (i) patient identification information,
    - (ii) CT scans performed along with the imaging parameters ,
    - (iii) the CT manufacturer's patient dose assessment, and
    - (iv) whether the study was conducted with contrast media.
    - (v) The logbook can be in electronic format provided all information is readily available to the Department during periodic inspections.
- (f) CT Radiation Protocol Committee (RPC).
- (1) The registrant must develop and maintain a CT RPC, or must allow its Radiation Safety Committee to assume such responsibility. Members of the RPC must include but not be limited to the:
    - (i) lead CT radiologist;
    - (ii) lead CT technologist;
    - (iii) QMP; and
    - (iv) other individuals as deemed necessary by the registrant (e.g., Radiation Safety Officer, Chief Medical or Administrative Officer, Radiology Department Administrator/Manager).
  - (2) The RPC must:
    - (i) review existing CT protocols along with the evaluation and implementation of new and innovative technologies that can improve image quality and lower patient dose in comparison with the older protocol.
    - (ii) review the capabilities of the individual CT scanner to ensure maximum performance is achieved.

- (iii) determine and review the protocols used frequently or which could result in significant doses. This review must include acquisition and reconstruction parameters and radiation dose. At a minimum, the facility must review the following clinical protocols, if performed, at intervals at least every 12 months:
  - (A) Pediatric Head;
  - (B) Pediatric Abdomen;
  - (C) Adult Head;
  - (D) Adult Abdomen;
  - (E) Adult Chest;
  - (F) Brain Perfusion.
- (iv) establish and implement written protocols, or protocols documented in an electronic reporting system, that include but are not limited to the following:
  - (A) a method to be used to monitor the CT radiation output.
  - (B) a standardized protocol naming policy.
  - (C) an alert dose value for CT procedures reviewed in clause (iii) of this paragraph must be established by the QMP.
  - (D) actions to be taken for cases when the alert dose value was exceeded, which may include patient follow-up.
  - (E) a process determining who has access and authority to make changes to the protocol management systems, including a method to prevent inadvertent or unauthorized modifications to a CT protocol.
- (v) if CT fluoroscopy is performed, the RPC must establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure.
- (vi) provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee.
- (vii) At a minimum the RPC members must meet as often as necessary to conduct business but at intervals not to exceed 12 months.
- (viii) A record of each RPC meeting must be maintained. The record must include the date, names of individuals in attendance, minutes of the meeting, and any action taken.
- (g) PET CT and SPECT CT systems. Registrants of CT systems used solely to calculate attenuation coefficients in nuclear medicine studies are exempt from the accreditation and quality assurance requirements of subdivisions (c) through (f) of this section. The registrant must follow the manufacturer's recommendations for the quality assurance tests to be conducted at the manufacturer's recommended frequency.
- (h) CT and CBCT units utilized in podiatry and veterinary offices. CT systems, including CBCT systems, solely used for podiatry imaging or non-human imaging must meet the requirements of radiation protection surveys as indicated in §175.16, and are otherwise exempt from the accreditation and quality assurance requirements of subdivisions (c) through (f) of this section. Facilities must follow the manufacturer recommended testing protocols and frequency as stated in the manufacturer's manual, and if any tests are shown to exceed manufacturer tolerances, the registrant must complete all required corrective actions within 30 days of such test.

**§175.60 Therapeutic radiation machines - general requirements.**

- (a) Administrative controls. The registrant must ensure that the requirements of this Article are met in the operation of the therapeutic radiation machine that is registered with the Department pursuant to §175.41.
- (b) A therapeutic radiation machine that does not meet the provisions of this Article shall not be used for irradiation of patients.
- (c) Authorized users. The authorized user of any therapeutic radiation machine must be a physician who:
  - (1) is certified in:

- (i) radiation oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or
- (ii) radiation oncology by the American Osteopathic Board of Radiology; or
- (iii) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
- (iv) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
- (v) radiation oncology by the National Board of Physicians and Surgeons; or
- (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 3 years of supervised clinical experience.
  - (i) To satisfy the requirement for instruction in this paragraph, classroom and laboratory training must include:
    - (A) radiation physics and instrumentation;
    - (B) radiation protection;
    - (C) mathematics pertaining to the use and measurement of ionization radiation; and
    - (D) radiation biology.
  - (ii) To satisfy the requirement for supervised work experience in this paragraph, training must be under the supervision of an authorized user and must include:
    - (A) review of the full calibration measurements and periodic quality assurance checks;
    - (B) evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
    - (C) use of administrative controls to prevent medical events;
    - (D) implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
    - (E) checking and using radiation survey meters.
  - (iii) To satisfy the requirement for a period of supervised clinical experience in this paragraph, training must include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience must include:
    - (A) examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
    - (B) selecting proper dose and how it is to be administered;
    - (C) calculating the therapeutic 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 or treatment plans as warranted by patients' reaction to radiation; and
    - (D) post-administration follow-up and review of case histories.
- (3) For certain therapeutic modalities, such as proton, neutron, carbon, helium or any other heavy ion therapy, authorized users must document training and experience together with the specific modality. The training must include device operation, safety procedures and clinical use of the therapy unit. This training requirement may be satisfied by satisfactory completion of a training program provided by the particular therapy unit vendor or by receiving training supervised by another authorized user or QMP, who is authorized for the use of such therapy unit modality.
- (4) Notwithstanding the other requirements of this section, the registrant for any therapeutic radiation machine may also submit the training of the prospective authorized user physician for Department review on a case-by-case basis.
- (5) 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 Department.

- (d) Qualifications of operators.
  - (1) Any person, other than a professional practitioner, who operates a therapeutic radiation machine for medical use shall be a licensed and registered radiation therapist, or a student currently enrolled in an approved program of study in radiation therapy technology and operating under the direct supervision of a professional practitioner or licensed radiation therapist.
  - (2) The names and training of all personnel currently operating a therapeutic radiation machine must be kept on file at the facility. Information on former operators must be retained for a period of at least 2 years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.
- (e) Written safety procedures and rules must be developed by a QMP and must be available in printed form in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator must be able to demonstrate familiarity with these rules.
- (f) Individuals must not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine authorized user. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.
- (g) Visiting authorized user. Notwithstanding other provisions of this section, 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 if:
  - (1) the visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee (where applicable); and
  - (2) the visiting authorized user meets the requirements established for authorized users in subdivision (c) of this section, and
  - (3) the registrant maintains copies of the written permission required by paragraph (1) of this subdivision and documentation that the visiting authorized user met the requirements of paragraph (2) of this subdivision for 5 years from the date of the last visit.
- (h) All individuals associated with the operation of a therapeutic radiation machine must be instructed in and must comply with the provisions of the registrant's quality assurance program. In addition to the requirements of this section, these individuals are also subject to the requirements of this Article.
- (i) Information and maintenance record and associated information. The registrant must maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Department:
  - (1) report of acceptance testing;
  - (2) records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machines required by this Article, as well as the names of persons who performed such activities;
  - (3) records of maintenance or modifications performed on the therapeutic radiation machine, as well as the names of persons who performed such services, and
  - (4) signature of person authorizing the return of the therapeutic radiation machine to clinical use after service, repair or upgrade.
- (j) Records retention. All records required by this section must be retained until disposal is authorized by the Department, or unless another retention period is specifically authorized. All required records must be retained in an active file from at least the time of generation until the next Department inspection. Any required record generated prior to the last Department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Department authorizes final disposal.

**§175.61 Therapeutic radiation machines - technical requirements.**

- (a) Radiation protection surveys.

- (1) The registrant must ensure that radiation protection surveys of all new facilities, and of existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated in accordance with §175.66. The radiation protection survey must be performed by, or under the direction of, a QMP and must 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, that radiation levels in both restricted and unrestricted areas are not likely to cause personnel exposures in excess of the limits specified in this Article.
- (2) In addition to the requirements of paragraph (1) of this subdivision, a radiation protection survey must also be performed prior to any subsequent medical use and:
  - (i) after making any change in the treatment room shielding;
  - (ii) after making any change in the location of the therapeutic radiation machine within the treatment room;
  - (iii) after relocating the therapeutic radiation machine; or
  - (iv) before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.
- (3) The survey record must indicate all instances where the facility, in the opinion of the QMP is in violation of applicable requirements. The survey record must also include:
  - (i) the date of the measurements;
  - (ii) the reason the survey is required;
  - (iii) the survey instrument manufacturer's name;
  - (iv) model number and serial number of the therapeutic radiation machine;
  - (v) the beam parameters in use;
  - (vi) the instruments used to measure radiation levels;
  - (vii) a plan of the areas surrounding the treatment room that were surveyed;
  - (viii) the measured dose rate at several points in each area expressed in microsieverts or millirems per hour;
  - (ix) the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and
  - (x) the signature of the individual responsible for conducting the survey.
- (4) If the results of the surveys required by this subdivision indicate any radiation levels in excess of the respective limit specified in this Article, the registrant must lock the control in the "OFF" position and not use the unit, 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 until the registrant has received a specific exemption from the Department.
- (b) Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by subdivision (a) of this section indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by this Article, before beginning the treatment program, the registrant must:
  - (1) either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with this Article;
  - (2) perform the survey required by subdivision (a) of this section again; and
  - (3) include in the report required by subdivision (d) of this section, the results of the initial survey, a description of the modification made to comply with paragraph (1) of subdivision (b) of this section, and the results of the second survey; or
  - (4) request and receive a registration amendment under this Article that authorizes radiation levels in unrestricted areas greater than those permitted by this Article.
- (c) Dosimetry equipment.
  - (1) The registrant must have a calibrated dosimetry system available for use. The system must have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory



(ADCL). The calibration must have been performed within the previous 24 months and after any servicing that may have affected system calibration.

- (i) for beams with energies greater than 1 MV (1 MeV), the dosimetry system must have been calibrated for Cobalt-60;
- (ii) for beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system must have been calibrated at an energy (energy range) appropriate for the radiation being measured.
- (2) The registrant must have available for use a dosimetry system to perform quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (1) of this subdivision. This comparison must 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 paragraph (1) of this subdivision.
- (3) The registrant must maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record must include:
  - (i) the date;
  - (ii) the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by paragraphs (1) and (2) of this subdivision
  - (iii) the correction factors that were determined;
  - (iv) the names of the individuals who performed the calibration, intercomparison, or comparison; and
  - (v) evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a QMP.
- (d) Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to §§175.64 or 175.65 must furnish a copy of the records required by subdivisions (a) and (b) of this section to the Department within 30 days following completion of the action that initiated the record requirement.

**§175.62 Therapeutic radiation machines - quality assurance requirements.**

Each registrant or applicant subject to the requirements of §§175.64, 175.65 or 175.69 must develop, implement and maintain a quality assurance program to provide assurance that radiation will be administered as directed by the authorized user.

- (a) The quality assurance program must include all of the policies and procedures listed in §175.108(c). In addition, the written directive described in §175.108(c)(2)(ii) must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site and number of fractions. The registrant must retain a copy of the written directive for 3 years.
- (b) Each registrant must adopt and maintain a radiation treatment planning manual prepared by a QMP. The manual must include the calculation methods and formulas to be used at the facility. The treatment planning manual shall be part of the registrant's quality assurance program required by subdivision (a) of this section. The radiation treatment manual must be included in training given pursuant to §175.11(c) to facility staff who will participate in treatment planning. Each registrant must ensure that a QMP reviews and approves the treatment planning manual at least annually.
- (c) Accreditation in radiation oncology (except superficial therapeutic x-ray units).
  - (1) Each registrant must have an active application with, or be accredited in radiation oncology by the American College of Radiology or the American College of Radiation Oncology or the American Society for Radiation Oncology or another accrediting organization that is equivalent as determined by the Department.
  - (2) The registrant must maintain a record of accreditation, including a copy of the application, all supplemental application information and all correspondence transmitted between the accrediting body and the registrant or licensee. Records must be maintained for at least 6 years.

- (d) A certified registrant must make a record of, but not report, a therapeutic radiation dose when errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final prescribed total treatment dose ordered by more than 10 percent.
- (e) A certified registrant must report any event resulting from intervention of a patient or human research subject in which the administration of radiation results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

**§175.63 Therapeutic radiation machines - medical events.**

- (a) For a medical event involving therapeutic radiation machines, in addition to the requirements of §175.25, the certified registrant must provide notification of a 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 certified registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The certified 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 certified registrant must notify the individual as soon as possible thereafter. The certified registrant must 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 subdivision, 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 certified registrant must inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The certified registrant must provide such a written description if requested.
- (b) Aside from the notification requirements of this section, nothing in this section affects any rights or duties of certified registrants and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.
- (c) Records of medical events. A registrant must retain a record of medical events for 3 years. The record must contain the following:
  - (1) the registrant's name and the names of the individuals involved;
  - (2) the patient identification number, if one has been assigned, of the individual who is the subject of the event;
  - (3) a brief description of the event; why it occurred; the effect, if any, on the individual;
  - (4) the actions, if any, taken or planned to prevent recurrence; and
  - (5) whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

**§175.64 Therapeutic radiation machines of less than 500 kV.**

This section applies to photon therapy systems not capable of operating at 500kV and above, and to electron therapy systems not capable of operating at 500 keV and above. The requirements of this section do not apply to electronic brachytherapy devices.

- (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 must not exceed the value specified at the distance specified for that classification of therapeutic radiation machine, as follows:
  - (1) for 5-50 kV Systems, the leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly must not exceed 1 mGy (100 mrad) in any one hour.
  - (2) for >50 and <500 kV Systems, the leakage air kerma rate measured at a distance of 1 meter from the target in any direction must not exceed 1 cGy (1 rad) in any 1 hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters (100 cm<sup>2</sup>). In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly must not exceed 30 cGy (30 rad) per hour.

- (3) For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs (1) and (2) of this subdivision for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Department.
- (b) Permanent beam limiting devices. Permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.
- (c) Adjustable or removable beam limiting devices.
- (1) All adjustable or removable beam limiting devices, diaphragms, cones or blocks must not transmit more than 5 percent 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 must be indicated by a light beam.
- (d) Filter system. The filter system must be so designed that:
- (1) filters cannot be accidentally displaced at any possible tube orientation;
- (2) for equipment installed after August 1, 1994, an interlock system prevents irradiation if the proper filter is not in place;
- (3) the air kerma rate escaping from the filter slot must not exceed 1 cGy (1 rad) per hour at 1 meter under any operating conditions; and
- (4) each filter must be marked as to its material of construction and its thickness.
- (e) Tube immobilization.
- (1) The x-ray tube must be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and
- (2) the tube housing assembly must be capable of being immobilized for stationary portal treatments.
- (f) Source marking. The tube housing assembly must be so marked that it is possible to determine the location of the source to within 5 millimeters and such marking must be readily accessible for use during calibration procedures.
- (g) Beam block. Contact therapy tube housing assemblies must 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 must be provided to terminate the irradiation after a pre-set time interval.
- (1) A timer with a display must be provided at the treatment control panel. The timer must have a pre-set time selector and an elapsed time or time remaining indicator;
- (2) the timer must be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator;
- (3) the timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
- (4) the timer must permit accurate pre-setting and determination of exposure times as short as 1 second;
- (5) the timer must not permit an exposure if set at zero;
- (6) the timer must not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and
- (7) the timer must be accurate to within 1 percent of the selected value or 1 second, whichever is greater.
- (i) Control panel functions. The control panel, in addition to the displays required by other provisions in this section, must have:
- (1) an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
- (2) an indication of whether x-rays are being produced;
- (3) a 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 installed after August 1, 1994, a positive display of specific filters in the beam.
- (j) Multiple tubes. When a control panel may energize more than one x-ray tube:
  - (1) it must be possible to activate only one x-ray tube at any time;
  - (2) there must be an indication at the control panel identifying which x-ray tube is activated; and
  - (3) there must be an indication at the tube housing assembly when that tube is energized.
- (k) Target-to-Skin Distance (TSD). There must be a means of determining the central axis TSD to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.
- (l) Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam must be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter must be controlled by the operator from the control panel. An indication of shutter position must appear at the control panel.
- (m) Low filtration x-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window must be clearly labeled as such upon the tube housing assembly and must be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.
- (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 the requirements of §175.67, the treatment room must meet the following design requirements:
  - (1) Aural communication. Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel;
  - (2) Viewing systems. Provision must be made to permit continuous observation of the patient during irradiation and the viewing system must be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational.
- (o) Additional requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV must meet the following additional requirements:
  - (1) all protective barriers must be fixed except for entrance doors or beam interceptors;
  - (2) the control panel must be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
  - (3) interlocks must be provided such that all entrance doors, including doors to any interior booths, must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
  - (4) when any door referred to in paragraph (3) of this subdivision is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source must 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 this section must be performed by, or under the direct supervision of, a QMP:
    - (i) before the first medical use following installation or reinstallation of the therapeutic radiation machine;
    - (ii) at intervals not exceeding 1 year; and
    - (iii) before medical use under the following conditions:
      - (A) whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

- (B) following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
- (iv) Notwithstanding the requirements of subparagraphs (i) – (iii) of this paragraph:
  - (A) full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes or energies that are not within their acceptable range; and
  - (B) if the repair, replacement or modification does not affect all energies, full calibration must be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in subparagraph (iii) of this paragraph.
- (2) To satisfy the requirements of paragraph (1) of this subdivision, full calibration must 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) or the most current revision or successor national standard.
- (3) The registrant must maintain a record of each calibration for the duration of the registration. The record must include:
  - (i) the date of the calibration;
  - (ii) the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;
  - (iii) the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
  - (iv) the signature of the QMP responsible for performing the calibration.
- (q) Periodic quality assurance checks.
  - (1) Periodic quality assurance checks must be performed on therapeutic radiation machines subject to the requirements of this section, which are capable of operation at greater than or equal to 50 kV.
  - (2) To satisfy the requirement of paragraph (1) of this subdivision, quality assurance checks must meet the following requirements:
    - (A) the registrant must perform quality assurance checks in accordance with written procedures established by the QMP; and
    - (B) the quality assurance check procedures must specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures must specify that the quality assurance check must be performed during the calibration specified in paragraph (1) of subdivision (p) of this section. The acceptable tolerance must be stated for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in paragraph (1) of subdivision (p) of this section.
  - (3) The cause for a parameter exceeding a tolerance set by the QMP must 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 QMP's quality assurance check procedures, the system must be recalibrated as required in paragraph (1) of subdivision (p) of this section;
  - (5) The registrant must use the dosimetry system described in §175.61(c)(2) to make the quality assurance check required in paragraph (2) of this subdivision;
  - (6) The registrant must have the QMP 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 must ensure that safety quality assurance checks of therapeutic radiation machines subject to the requirements of this section are performed at intervals not to exceed 30 days;
  - (8) Notwithstanding the requirements of paragraphs (6) and (7) of this subdivision, the registrant must ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by paragraphs (1) and (2) of this subdivision have been performed within the 30 day period immediately prior to said administration;

- (9) To satisfy the requirement of paragraph (7) of this subdivision, safety quality assurance checks must ensure proper operation of:
- (i) electrical interlocks at each external beam radiation therapy room entrance;
  - (ii) the "BEAM-ON" and termination switches;
  - (iii) beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
  - (iv) viewing systems;
  - (v) electrically operated treatment room doors from inside and outside the treatment room, if applicable.
- (10) The registrant must maintain a record of each quality assurance check required by paragraphs (1) and (7) of this subdivision for 3 years. The record must include:
- (i) the date of the quality assurance check;
  - (ii) the manufacturer's name, model number, and serial number of the therapeutic radiation machine;
  - (iii) the manufacturer's name, model number and serial number for the instrument used to measure the radiation output of the therapeutic radiation machine; and
  - (iv) the signature of the individual who performed the periodic quality assurance check
- (r) Operating procedures.
- (1) The therapeutic radiation machine must not be used for irradiation of patients unless the requirements of subdivisions (p) and (q) of this section have been met.
  - (2) Therapeutic radiation machines must not be left unattended unless secured pursuant to paragraph (5) of subdivision (i) of this section.
  - (3) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used.
  - (4) The tube housing assembly must 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 must wear protective gloves and apron of not less than 0.25 millimeters lead equivalency at 100 kV.
  - (5) A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console.
  - (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 must be protected by a barrier sufficient to meet the requirements of this Article.
- (s) Possession of survey instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with this section must possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument must be operable and calibrated in accordance with §175.66.

**§175.65 Therapeutic radiation machines above 500 kV.**

This section applies to photon therapy systems capable of operating at 500kV and above, electron therapy systems capable of operating at 500 keV and above, and proton therapy systems.

- (a) Possession of survey instrument. Each facility location authorized to use a therapeutic radiation machine subject to this section must possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument must be operable and calibrated in accordance with §175.66.
- (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 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), must not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters (100 cm<sup>2</sup>) at a minimum of 16 points uniformly distributed in the plane;
  - (2) Except for the area defined in paragraph (1) of this subdivision, the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window must not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters (100 cm<sup>2</sup>);
  - (3) For equipment manufactured after July 1, 2019, the neutron absorbed dose outside the useful beam must comply with International Electrotechnical Commission (IEC) Document 60601-2-1 (or the most current revision or successor national standard); and
  - (4) For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs (1) and (2) of this subdivision for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Department.
- (c) Leakage radiation through beam limiting devices.
- (1) Photon radiation. All adjustable jaws type beam limiting devices must attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device must not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm<sup>2</sup> radiation field, or maximum available field size if less than 100 cm<sup>2</sup>.
  - (2) Electron radiation. All adjustable or interchangeable electron applicators must attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance must not exceed:
    - (i) a maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit applies beyond a line 7 centimeters outside the periphery of the useful beam; and
    - (ii) a maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit applies beyond a line 2 centimeters outside the periphery of the useful beam.
  - (3) Skyshine radiation. The exposure due to neutron and photon emissions scattered outside the facility must be calculated using industry standard methods.
  - (4) Measurement of leakage radiation.
    - (i) Photon radiation. Measurements of leakage radiation through the beam limiting devices must be made with the beam limiting devices closed and any residual aperture blocked by at least 2-tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set must be measured independently at the depth of maximum dose. Measurements must be made using a radiation detector of area not exceeding 10 square centimeters (10 cm<sup>2</sup>).
    - (ii) Electron radiation. Measurements of leakage radiation through the electron applicators must be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding 1 square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements must be made using 1 centimeter of water equivalent build up material.
- (d) Filters/wedges.

- (1) Each wedge filter that is removable from the system must be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle must appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor must be re-measured.
- (2) If the absorbed dose rate information required by subdivision (i) of this section relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter must be removable only by the use of tools.
- (3) For equipment which utilizes wedge filters manufactured after July 1, 2019, interchangeable field flattening filters, or interchangeable beam scattering foils, the following apply:
  - (i) irradiation must not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
  - (ii) an interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;
  - (iii) a display must be provided at the treatment control panel showing the wedge filter, interchangeable field flattening filters, or interchangeable beam scattering foils in use; and
  - (iv) an interlock must be provided to prevent irradiation if any filter or beam scattering foil selection operation carried out in the treatment room does not agree with the filter or beam scattering foil selection operation carried out at the treatment control panel.
- (e) Stray radiation in the useful beam. For equipment manufactured after July 1, 2019, the registrant must 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 comply with International Electrotechnical Commission (IEC) Document 60601-2-1 (or the most current revision or successor national standard).
- (f) Beam monitors. All therapeutic radiation machines subject to the requirements of this section must be provided with redundant beam monitoring systems. The sensors for these systems must be fixed in the useful beam during treatment to indicate the dose monitor unit rate.
  - (1) Equipment manufactured after July 1, 2019 must be provided with at least 2 independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.
  - (2) Equipment manufactured on or before July 1, 2019 must be provided with at least 1 radiation detector. This detector must be incorporated into a useful beam monitoring system.
  - (3) The detector and the system into which that detector is incorporated must meet the following requirements:
    - (i) each detector must be removable only with tools and, if movable, must be interlocked to prevent incorrect positioning;
    - (ii) each detector must form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;
    - (iii) each beam monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation; and
    - (iv) for equipment manufactured after July 1, 2019, the design of the beam monitoring systems must ensure that the:
      - (A) malfunctioning of one system must not affect the correct functioning of the other systems; and
      - (B) failure of either system must terminate irradiation or prevent the initiation of radiation.
  - (v) each beam monitoring system must have a legible display at the treatment control panel. For equipment manufactured after July 1, 2019, each display must:
    - (A) maintain a reading until intentionally reset;
    - (B) have only one scale and no electrical or mechanical scale multiplying factors;
    - (C) utilize a design such that increasing dose is displayed by increasing numbers; and



- (D) in the event of power failure, the beam monitoring information required by subparagraph (v) of paragraph (3) of this subdivision displayed at the control panel at the time of failure must be retrievable in at least one system for a 20 minute period of time.
- (g) Beam symmetry.
- (1) A bent-beam linear accelerator with beam flattening filters subject to the requirements of this section must be provided with auxiliary devices to monitor beam symmetry;
  - (2) The devices referenced in paragraph (1) of this subdivision must be able to detect field asymmetry greater than 10 percent; and
  - (3) The devices referenced in paragraph (1) of this subdivision must be configured to terminate irradiation if the specifications in paragraph (2) of this subdivision cannot be maintained.
- (h) Selection and display of dose monitor units.
- (1) Irradiation must 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 must be displayed at the treatment control panel until reset manually for the next irradiation.
  - (3) After termination of irradiation, it must be necessary to reset the dosimeter display before subsequent treatment can be initiated.
  - (4) For equipment manufactured after July 1, 2019 after termination of irradiation, it must be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.
- (i) Air kerma rate/absorbed dose rate. For equipment manufactured after July 1, 2019, a system must be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. In addition, the following requirements apply:
- (1) the dose monitor unit rate must be displayed at the treatment control panel;
  - (2) if the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device must be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The registrant must maintain a record of dose rate at which the irradiation will be terminated;
  - (3) if the equipment can deliver under any fault conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device must be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and
  - (4) for each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the maximum values specified in paragraphs (2) and (3) of §175.65(i) for the specified operating conditions. Records of these maximum values must be maintained at the installation for inspection by the Department.
- (j) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.
- (1) Each primary system must 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 must be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.
  - (3) For equipment manufactured after July 1, 2019, an indicator on the control panel must show which monitoring system has terminated irradiation.

- (k) Termination of irradiation. It must be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.
- (l) Interruption of irradiation. If a therapeutic radiation machine has an interrupt mode, it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption, it must be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements must be automatically terminated.
- (m) Timer. A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval.
- (1) A timer must be provided which has a display at the treatment control panel. The timer must have a pre-set time selector and an elapsed time indicator.
  - (2) The timer must be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator.
  - (3) The timer must 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 must meet the following additional requirements:
- (1) irradiation must not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;
  - (2) the radiation type selected must be displayed at the treatment control panel before and during irradiation;
  - (3) an interlock system must be provided to:
    - (i) ensure that the equipment can principally emit only the radiation type that has been selected;
    - (ii) prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;
    - (iii) prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
    - (iv) 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 must meet the following requirements:
- (1) irradiation must not be possible until a selection of energy has been made at the treatment control panel;
  - (2) the nominal energy value selected must be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it must be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;
  - (3) irradiation must not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and
  - (4) for equipment manufactured after July 1, 2019, the selection of energy must comply with International Electrotechnical Commission (IEC) Document 60601-2-1 (or the most current revision or successor national standard).
- (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 must meet the following requirements:
- (1) irradiation must not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
  - (2) the mode of operation must be displayed at the treatment control panel;
  - (3) an interlock system must be provided to ensure that the equipment can operate only in the mode that has been selected;

- (4) an interlock system must be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
- (5) moving beam radiation therapy must be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 1, 2019:
  - (i) an interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 cm of linear motion differs by more than 20 percent from the selected value;
  - (ii) where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than 5 percent from the dose monitor unit value selected;
  - (iii) an interlock must be provided to prevent motion of more than 5 degrees or 1 cm beyond the selected limits during moving beam radiation therapy;
  - (iv) an interlock must be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy; and
  - (v) moving beam radiation therapy must be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.
- (6) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation must be as required by subdivision (j) of this section.
- (7) For equipment manufactured after July 1, 2019, an interlock system must be provided to terminate irradiation if movement:
  - (i) occurs during stationary beam radiation therapy; or
  - (ii) does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.
- (q) Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to the shielding requirements of §175.67, the following design elements are required:
  - (1) Protective barriers. All protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors.
  - (2) Control panel. In addition to other requirements specified in this Article, the control panel must also:
    - (i) be located outside the treatment room;
    - (ii) provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
    - (iii) provide an indication of whether radiation is being produced; and
    - (iv) include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.
  - (3) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system must be provided to permit continuous observation of the patient following positioning and during irradiation and must be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational.
  - (4) Aural communications. Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine must not be used for irradiation of patients unless continuous two-way aural communication is possible.
  - (5) Room entrances. Treatment room entrances must be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".
  - (6) Entrance interlocks. Interlocks must be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control,

- it must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.
- (7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with this Article, interlocks must be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier.
  - (8) Emergency cutoff switches. At least 1 emergency power cutoff switch must be located in the radiation therapy room and must terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subdivision (k) of this section. All emergency power cutoff switches must include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.
  - (9) Safety interlocks. All safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.
  - (10) Surveys for residual radiation. Surveys for residual activity must be conducted on all therapeutic radiation machines capable of generating photon and electron energies, or proton 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.
  - (11) Applicants for proton therapy systems capable of operating at 500 keV and above must present documentation of shielding design adequate as determined by the Department to meet the requirements of §175.67. An independent consultant qualified in proton shielding calculation with proven experience in applicable computer simulation, not involved in the original design and with prior approval by the Department must be hired by the applicant to perform an independent verification of the proposed shielding design using site specific equipment and data or information. The independent consultant must prepare a report evaluating the correctness and completeness of the original shielding design calculation, and the adequacy of the shielding design to satisfy the requirements of §175.67. The independent consultant's report must be submitted to the Department by the applicant as an addendum to the application.
- (r) QMP support.
- (1) The services of a QMP must be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The QMP must be responsible for:
    - (i) full calibrations required by subdivision (t) of this section and protection surveys required by §175.61(a);
    - (ii) supervision and review of patient dosimetry;
    - (iii) beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
    - (iv) quality assurance, including quality assurance check review required by paragraph (5) of subdivision (u) of this section;
    - (v) consultation with the authorized user in treatment planning, as needed; and
    - (vi) perform calculations/assessments regarding medical events.
  - (2) If the QMP is not a full-time employee of the registrant, the operating procedures required by subdivision (s) of this section must also specifically address how the QMP is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the QMP can be contacted.
  - (3) Notwithstanding other provisions of this Article, the QMP named on the certified registration for a proton therapy machine described in this section must be a full-time employee of the registrant.
- (s) Operating procedures.
- (1) No individual, other than the patient, must be in the treatment room during treatment or during any irradiation for testing or calibration purposes.

- (2) Therapeutic radiation machines must not be made available for medical use, unless the requirements of subdivision (a) of §175.61 and subdivisions (t) and (u) of this section have been met.
- (3) Therapeutic radiation machines, when not in operation, must be secured to prevent unauthorized use.
- (4) When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field.
- (5) If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used.
- (6) A copy of the current operating and emergency procedures must 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 this section must be performed by, or under the direct supervision of, a QMP.
  - (2) Acceptance testing and commissioning must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47", prepared by Radiation Therapy Task Group 45 (or the most current revision or successor national standard) and the manufacturer's contractual specifications. Acceptance testing and commissioning must be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.
  - (3) Full calibration for photon therapy systems capable of operating at 500 kV and above or electron therapy systems capable of operating at 500 keV and above must include measurement of all applicable parameters required by Table II of the "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: AAPM Report No. 46," prepared by Committee Task Group 40 and must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47" prepared by Radiation Therapy Task Group 45 (or the most current revision or successor national standard). Although it is not necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) must be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.
  - (4) For proton therapy systems capable of operating at 500 keV and above, full calibration must include measurement of all applicable parameters. The certified registrant must submit their full calibration protocol to the Department for review and approval.
  - (5) The QMP must perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits when the following apply:
    - (i) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy or multi-mode capabilities shall only require measurements for those modes or energies that are not within their acceptable range.
    - (ii) 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 or energies, measurements must 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 subparagraph (i) of this paragraph (5) of this subdivision (t) of this section.
  - (6) The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include:
    - (i) the date of the calibration, the manufacturer's name, model and serial number or other unambiguous identification of the therapeutic radiation machine along with the instrument's certificate of calibration and;

- (ii) all measured beam output data collected during the calibration and the derivation for all the correction factors (as delineated in AAPM Reports TG 21 or TG 51 or any successor publication or national standard) applied to the measured beam output data in the calculation of the therapeutic radiation machine's beam output dose rate (the latter must be conducted for each photon and electron beam clinically utilized at the facility).
  - (iii) for photon or electron therapy machines, the derivation of all the correction factors applied to the measured beam output data in the calculation of the therapeutic radiation machine's beam output dose rate (as delineated in AAPM Reports TG 21 or TG 51 or any successor publication or national standard) or;
  - (iv) for proton therapy machines, derivation for all the correction factors applied to the measured beam output data in the calculation of the therapeutic radiation machine's beam output dose rate (as delineated in the registrant's calibration protocol). The certified registrant's calibration protocol in the case of proton therapy machines must be submitted to Department for review and approval.
- (u) Periodic quality assurance checks.
- (1) Periodic quality assurance checks must be performed on all therapeutic radiation machines subject to this section. To satisfy this requirement, quality assurance checks must include a determination of all parameters for periodic quality assurance checks and at the intervals contained in AAPM Task Group 142 report: "Quality assurance of medical accelerators" (2009) (or the most current revision or successor national standard) for photon therapy systems capable of operating at 500 kV and above or electron therapy systems capable of operating at 500 keV and above.
  - (2) The registrant must use a dosimetry system that has been compared within the previous 12 months with the dosimetry system described in §175.61(c)(1) to make the periodic quality assurance checks required by paragraph (1) of this subdivision;
  - (3) The registrant must perform periodic quality assurance checks required by paragraph (1) of this subdivision in accordance with procedures established by the QMP;
  - (4) The registrant must review the results of each periodic radiation output check according to the following procedures:
    - (i) the QMP must be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine must not be made available for subsequent medical use until the QMP has determined that all parameters are within their acceptable tolerances;
    - (ii) if all quality assurance check parameters appear to be within their acceptable range, the quality assurance check must be reviewed and signed by either the authorized user or QMP within 3 treatment days; and
    - (iii) the QMP must review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.
  - (5) Therapeutic radiation machines subject to the requirements of this section must have applicable safety quality assurance checks listed in AAPM Task Group 142 report: "Quality assurance of medical accelerators" (2009) (or the most current revision or successor national standard) performed at intervals not to exceed 1 week;
  - (6) To satisfy the requirement of paragraph (5) of this subdivision, safety quality assurance checks must ensure proper operation of:
    - (i) electrical interlocks at each external beam radiation therapy room entrance;
    - (ii) proper operation of the "BEAM-ON", interrupt and termination switches;
    - (iii) beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
    - (iv) viewing systems;
    - (v) electrically operated treatment room doors from inside and outside the treatment room;

- (7) The registrant must annually perform checks to ensure proper operation of all emergency power cutoff switches, or documentation of proper operation of emergency power cutoff switches must be provided by the manufacturer as confirmed during preventative maintenance.
- (8) The registrant must promptly repair any system identified in paragraph (6) or (7) of this subdivision that is not operating properly
- (9) The registrant must maintain a record of each quality assurance check required by paragraphs (1), (6), and (7) of this subdivision for 3 years. The record must include:
  - (i) the date of the quality assurance check;
  - (ii) the manufacturer's name, model number, and serial number of the therapeutic radiation machine;
  - (iii) the manufacturer's name, model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and
  - (iv) the signature of the individual who performed the quality assurance check.
- (v) Possession of survey instruments.
  - (1) Each facility location authorized to use a therapeutic radiation machine in accordance with §175.65 must possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments must be operable and calibrated in accordance with §175.66.
  - (2) Each facility location authorized to use a proton therapeutic radiation machine must possess appropriately calibrated portable neutron radiation measuring equipment in accordance with §175.66.
- (w) Quality assurance checks for Intensity-Modulated Radiation Therapy (IMRT) must:
  - (1) include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans; and
  - (2) be performed in accordance with "Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82" (or the most current revision or successor national standard); and
  - (3) be performed in accordance with the manufacturer's specifications.

**§175.66 Therapeutic radiation machines; calibration of survey instruments.**

- (a) The registrant must ensure that the survey instruments used to show compliance with this Article have been calibrated before first use, and annually thereafter, and following repair.
- (b) To satisfy the requirements of subdivision (a) of this section, the registrant must:
  - (1) calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);
  - (2) calibrate at least 2 points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale.
- (c) To satisfy the requirements of subdivision (b) of this section., the registrant must:
  - (1) consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and
  - (2) consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.
- (d) The registrant must retain a record of each calibration required by subdivision (a) of this section for 3 years. The record must include:
  - (1) a description of the calibration procedure; and
  - (2) a description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

- (e) The registrant may obtain the services of individuals licensed by the Department, the US Nuclear Regulatory Commission or an Agreement State to perform calibrations of survey instruments. The registrant must maintain records of calibrations that contain information required by subdivision (d) of this section.

**§175.67 Therapeutic radiation machines; shielding and safety design requirements.**

- (a) Each therapeutic radiation machine subject to the requirements of §§175.64 or 175.65 must be provided with such primary and secondary barriers as are necessary to ensure compliance with this Article.
- (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 must be submitted for Department review prior to operation of the therapeutic radiation machine. The minimum facility design information that must be submitted to the Department is contained in Appendix A to this section:

**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 structures.**

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

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

**II. Therapeutic Radiation Machines up to 150 Kv (photons only).**

**In addition to the requirements listed in Section I, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV must 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 1 meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;**

**C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation ports; each port's travel and traverse limits; general direction 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 must be noted on the plan and the operator's station at the control panel must be behind a protective barrier sufficient to ensure compliance with this Article;**

**D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the rooms concerned;**

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



F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary/leakage barriers, restricted and unrestricted areas, entry doors) 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.

### III. Therapeutic Radiation Machines Over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV or electrons must 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 and types of radiation produced (i.e., photon, electron). The target to isocenter distance must be specified;

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

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], types, thickness and minimum density of shielding materials, direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the doors and maze;

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the rooms concerned;

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

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), work-load, presence of integral beam-stop in unit, occupancy and use 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; and

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors 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; and

(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, therapeutic radiation machine facilities that are capable of operating above 10 MV must 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 (i.e., restricted and unrestricted areas, entry doors and maze) and neutron shielding material utilized in the facility:

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

(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.

D. The methods and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

**§175.68 Therapeutic radiation machines – quality assurance for simulation systems.**

Quality assurance for a conventional or virtual simulator must include acceptance testing and periodic verification of system performance. This testing and verification must:

(a) be performed in accordance with "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No.40: AAPM Report No. 46" (or the most current revision or successor national standard) for a conventional simulator; or

(b) 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" (or the most current revision or successor national standard) for a virtual simulator.

**§175.69 Therapeutic radiation machines – electronic brachytherapy.**

(a) Applicability.

(1) An electronic brachytherapy device that does not meet the requirements of this section must not be used for irradiation of patients.

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

(3) Electronic brachytherapy devices are exempt from the requirements of §175.64.

(b) Possession of survey instruments. Each facility location authorized to use an electronic brachytherapy device in accordance with this section must possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments must be operable and calibrated in accordance with §175.66 for the applicable electronic brachytherapy source energy.

(c) Facility design requirements. In addition to shielding adequate to meet the requirements of §175.67, an electronic brachytherapy device treatment room must meet the following design requirements:

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

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

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

(4) For electronic brachytherapy devices capable of operating below 150 kV, radiation shielding for the staff in the treatment room must be available, either as a portable shield or as localized shielded material around the treatment site.

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

(i) the control panel must be located outside the treatment room; and

(ii) electrical interlocks must be provided for all doors to the treatment room that will:

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

- (B) cause the source to be shielded when an entrance door is opened; and
  - (C) prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.
- (d) Control panel. The control panel, in addition to the displays required by other provisions in this section, must:
  - (1) provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;
  - (2) provide an indication of whether x-rays are being produced;
  - (3) provide a means for indicating electronic brachytherapy source potential and current;
  - (4) provide the means for terminating an exposure at any time; and
  - (5) include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.
- (e) Timer. A suitable irradiation control device (timer) must be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.
  - (1) A timer must be provided at the treatment control panel. The timer must indicate planned setting and the time elapsed or remaining.
  - (2) The timer must not permit an exposure if set at zero.
  - (3) The timer must be a cumulative device that activates with an indication of "BEAM- ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator before irradiation can be resumed.
  - (4) The timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.
  - (5) The timer must permit setting of exposure times as short as 0.1 second.
  - (6) The timer must be accurate to within 1 percent of the selected value or 0.1 second, whichever is greater.
- (f) QMP support.
  - (1) The services of a QMP must be required in facilities having electronic brachytherapy devices. The QMP must be responsible for:
    - (i) evaluation of the output from the electronic brachytherapy source;
    - (ii) generation of the necessary dosimetric information;
    - (iii) supervision and review of treatment calculations prior to initial treatment of any treatment site;
    - (iv) establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required by subdivision (j) of this section;
    - (v) consultation with the authorized user in treatment planning, as needed; and
    - (vi) performing calculations/assessments regarding patient treatments that may constitute a medical event.
  - (2) If the QMP is not a full-time employee of the registrant, the operating procedures required by subdivision (g) of this section must also specifically address how the QMP is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the QMP can be contacted.
- (g) Operating procedures.
  - (1) Electronic brachytherapy devices must not be made available for medical use, unless the requirements of §175.61(a) and subdivisions (i) and (j) of this section have been met.
  - (2) The electronic brachytherapy device must be inoperable, either by hardware or password, when unattended by qualified staff or service personnel.
  - (3) Only individuals approved by the authorized user, radiation safety officer, or QMP shall be present in the treatment room during treatment.

- (4) During operation, the electronic brachytherapy device operator must monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam.
  - (5) If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used.
  - (6) Written procedures must be developed, implemented, and maintained for responding to equipment malfunction and any deviation from expected clinical outcomes. These procedures must include:
    - (i) instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
    - (ii) the names and telephone numbers of the authorized users, the QMP, and the radiation safety officer to be contacted if the device or console operates abnormally.
  - (7) A copy of the current operating and emergency procedures must be physically located at the electronic brachytherapy device control console. If the control console is integral to the electronic brachytherapy device, the required procedures must be kept where the operator is located during electronic brachytherapy device operation.
  - (8) Instructions must be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the QMP, and the radiation safety officer to be contacted if the device or console operates abnormally.
  - (9) The radiation safety officer or a designee, and an authorized user must be notified as soon as possible if a medical event occurs. The radiation safety officer or the QMP must inform the Department of the event.
- (h) Safety precautions.
- (1) A QMP must determine which persons in the treatment room require monitoring when the beam is energized.
  - (2) An authorized user and a QMP must be physically present during the initiation of all patient treatments involving the electronic brachytherapy device.
  - (3) A QMP and either an authorized user or a physician or electronic brachytherapy device operator, under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, must be physically present during continuation of all patient treatments involving the electronic brachytherapy device.
  - (4) When shielding is required by paragraph (4) of subdivision (c) of this section, the electronic brachytherapy device operator must use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a QMP must designate shield locations sufficient to meet the requirements of this Article for any individual, other than the patient, in the treatment room.
  - (5) All personnel in the treatment room are required to remain behind shielding during treatment. A QMP must approve any deviation from this requirement and must designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.
- (i) Source calibration measurements.
- (1) Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to this section must be performed by, or under the direct supervision of, a QMP.
  - (2) Calibration of the electronic brachytherapy source output must be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks.
  - (3) Calibration of the electronic brachytherapy source output must utilize a dosimetry system described in §175.61(c).
  - (4) Calibration of the electronic brachytherapy source output must include, as applicable, the determination of:
    - (i) the output within 2 percent of the expected value, if applicable, or determination of the output if there is no expected value;

- (ii) timer accuracy and linearity over the typical range of use;
- (iii) proper operation of back-up exposure control devices;
- (iv) evaluation that the relative dose distribution about the source is within 5 percent of that expected; and
- (v) source positioning accuracy to within 1 millimeter within the applicator;
- (5) Calibration of the x-ray source output required by paragraphs (1) through (4) of this subdivision must be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol must be followed.
- (6) The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include:
  - (i) the date of the calibration;
  - (ii) the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source;
  - (iii) the model numbers and serial numbers of the instrument used to calibrate the electronic brachytherapy device; and
  - (iv) the name and signature of the QMP responsible for performing the calibration.
- (j) Periodic and day-of-use quality assurance checks.
  - (1) Quality assurance checks must be performed on each electronic brachytherapy device subject to this section:
    - (i) at the beginning of each day of use;
    - (ii) each time the device is moved to a new room or site ("site" here is intended to include each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer); and
    - (iii) after each x-ray tube installation.
  - (2) The registrant must perform periodic quality assurance checks required by paragraph (1) of this subdivision in accordance with procedures established by the QMP.
  - (3) To satisfy the requirements of paragraph (1) of this subdivision, radiation output quality assurance checks must include as a minimum:
    - (i) verification that output of the electronic brachytherapy source falls within 3 percent of expected values, as appropriate for the device, as determined by:
      - (A) output as a function of time, or
      - (B) output as a function of setting on a monitor chamber.
    - (ii) verification of the consistency of the dose distribution to within 3 percent of that found during calibration required by subdivision (i) of this section.; and
    - (iii) validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within 1 mm; and
  - (4) The registrant must use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in §175.61(c)(1) to make the quality assurance checks required by paragraph (3) of this subdivision.
  - (5) The registrant must review the results of each radiation output quality assurance check according to the following procedures:
    - (i) an authorized user and QMP must be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device must not be made available for subsequent medical use until the QMP has determined that all parameters are within their acceptable tolerances
    - (ii) if all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check must be reviewed and signed by either the authorized user or QMP within 2 days; and

- (iii) the QMP must review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.
- (6) To satisfy the requirements of paragraph (1) of this subdivision, safety device quality assurance checks must, at a minimum, assure:
  - (i) proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
  - (ii) proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
  - (iii) proper operation of radiation monitors, if applicable;
  - (iv) the integrity of all cables, catheters or parts of the device that carry high voltages; and
  - (v) connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
- (7) If the results of the safety device quality assurance checks required by paragraph (6) of this subdivision indicate the malfunction of any system, a registrant must secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.
- (8) The registrant must maintain a record of each quality assurance check required by paragraphs (3) through (7) of this subdivision in an auditable form for 3 years.
  - (i) The record must include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check and the name and signature of the QMP who reviewed the quality assurance check;
  - (ii) For radiation output quality assurance checks required by paragraph (3) of this subdivision, the record must also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instruments used to measure the radiation output of the electronic brachytherapy device.
- (k) Therapy-related computer systems. The registrant must perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (if available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol must be followed.
  - (1) Acceptance testing must be performed by, or under the direct supervision of, a QMP. At a minimum, the acceptance testing must include, as applicable, verification of:
    - (i) the source-specific input parameters required by the dose calculation algorithm;
    - (ii) the accuracy of dose, dwell time, and treatment time calculations at representative points;
    - (iii) the accuracy of isodose plots and graphic displays;
    - (iv) the accuracy of the software used to determine radiation source positions from radiographic images; and
    - (v) if the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.
  - (2) The position indicators in the applicator must be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.
  - (3) Prior to each patient treatment regimen, the parameters for the treatment must be evaluated and approved by the authorized user and the QMP for correctness through means independent of that used for the determination of the parameters.
- (l) Training.
  - (1) A registrant must provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in subdivision (g) of this section. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

- (2) In addition to the requirements of subdivisions (c) of §175.60 as to authorized users, these individuals must also receive device specific instruction initially from the manufacturer and annually from either the manufacturer or other qualified trainer. The training must be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (if available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol must be followed. The training must include, but not be limited to:
- (i) device-specific radiation safety requirements;
  - (ii) device operation;
  - (iii) clinical use for the types of use approved by the FDA;
  - (iv) emergency procedures, including an emergency drill; and
  - (v) the registrant's quality assurance program.
- (3) A registrant must retain a record of individuals receiving instruction required by paragraphs (1) and (2) of this subdivision for 3 years. The record must include a list of the topics covered, the date of the instruction, the names of the attendees, and the names of the individuals who provided the instruction.
- (m) Mobile electronic brachytherapy service. A registrant providing mobile electronic brachytherapy service must, at a minimum:
- (1) check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive;
  - (2) account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address;
  - (3) perform, at each location on each day of use, all of the required quality assurance checks specified in subdivision (j) of this section to assure proper operation of the device.

**§175.70 Therapeutic radiation machines – other use of electronically-produced radiation.**

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

- (a) the applicant or registrant has, at a minimum, provided the Department with:
  - (1) a detailed description of the device and its intended application;
  - (2) facility design requirements, including shielding and access control;
  - (3) documentation of appropriate training for authorized user physicians and QMPs;
  - (4) methodology for measurement of dosages to be administered to patients or human research subjects;
  - (5) documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;
  - (6) radiation safety precautions and instructions; and
  - (7) other information requested by the Department in its review of the application; and
- (b) the applicant or registrant has received written approval from the Department to utilize the device in accordance with the requirements and specific conditions the Department considers necessary for the medical use of the device.

### PART III. RADIOACTIVE MATERIALS

#### **§175.100 Incorporation of federal regulations.**

- (a) All persons subject to the requirements of this Part (§§175.100 through 175.108) are required to comply with the specific provisions of Title 10 of the Code of Federal Regulations ("CFR") issued by the United States Nuclear Regulatory Commission ("NRC") as expressly indicated in this Part and which are hereby incorporated by reference herein to this Article with the same force and effect as if fully set forth herein in their entirety. For the purposes of this Part, such incorporation by reference shall mean the specific provisions of Title 10 of the CFR in effect as of the effective date of this Part, and any successor regulations promulgated by the NRC in Title 10 of the CFR expressly indicated in this Part. Any such successor regulation shall be considered adopted in this Part as of the effective date of the provision in the CFR.
- (b) In this Part (§§175.100 through 175.108), the following definitions apply:
- (1) "10 CFR" or "CFR" means Title 10 of the Code of Federal Regulations, Chapter I (Nuclear Regulatory Commission).
  - (2) "City" means the 5 boroughs of New York City.
  - (3) Except as indicated in subdivision (c) of this section, references to "Department" means the New York City Department of Health and Mental Hygiene.
  - (4) "Radioactive material" means any solid, liquid, or gas which spontaneously emits alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, or other particles capable of producing ions. For the purposes of this Part, radioactive material does not include material that emits only non-ionizing radiation, such as radiowaves or microwaves, visible, infrared or ultraviolet light.
- (c) To reconcile differences between this Article and the incorporated sections of the CFR, the following meanings are substituted for certain terms in the incorporated language of the CFR:
- (1) Except as indicated in paragraph (2) of this subdivision, any reference to "NRC" or "Commission" in the incorporated CFR regulations means the Department. Any notifications and correspondence required to be sent to the NRC in the incorporated regulations of the CFR should instead be sent to the Department at the address provided in §175.01(c).
  - (2) The following references to "NRC" or "Commission" in the incorporated CFR regulations shall continue to refer to and mean the Nuclear Regulatory Commission:
    - (i) References in 10 CFR §30.12 to Commission contractors;
    - (ii) References in 10 CFR Part 35 to Commission master material license or licensee;
    - (iii) References in 10 CFR Part 35 to the "NRC's web page" for listing of acceptable board certifications;
    - (iv) References in 10 CFR §37.27 relating to criminal history record checks;
    - (v) Reference in 10 CFR §37.29(a)(1) to "an employee of the Commission";
    - (vi) References in 10 CFR Part 71 to NRC-approved packaging.
  - (3) The references to "Department" in 10 CFR §§30.12 and 30.14(b)(1) means the U.S. Department of Energy.
  - (4) Any reference to "agreement state" within the incorporated CFR regulations means an external regulatory authority other than this Department.
  - (5) Any cross reference within the incorporated CFR regulations means a cross reference to the CFR unless otherwise specified; for example, a reference to "§30.18 of this Chapter" means "10 CFR §30.18."
  - (6) References to forms in the incorporated CFR regulations mean the appropriate forms prescribed by the Department.
- (d) The CFR provisions incorporated by reference herein may be obtained from:
- (1) the Department at the address provided in §175.01(c), or
  - (2) the United States Government Publishing Office (GPO), 710 North Capitol Street, N.W.,



- Washington, DC 20401 (866) 512-1800, or, online at <https://www.govinfo.gov/app/collection/cfr/2018/title10/chapterI/TOC>, or
- (3) the U.S. Nuclear Regulatory Commission online at <https://www.nrc.gov/reading-rm/doc-collections/cfr/>.

**§175.101 Notices, instructions and reports to workers.**

- (a) Except as set forth in subdivision (b) of this section, 10 CFR Part 19 is hereby incorporated by reference herein to this Article with the same force and effect as if fully set forth in its entirety.
- (b) The following provisions from 10 CFR Part 19 are not so incorporated: §19.1, §19.2, the definition of “regulated entities” in §19.3, §19.4, §19.5, §19.8, §§19.11(b)-(e), §19.14(a), §19.18, §19.30, §19.31, §19.32 and §19.40.
- (c) Additional requirements.
- (1) Instructions to workers as required in 10 CFR §19.12 must be given to all individuals working in or frequenting any portion of a restricted area.
- (2) In addition to the requirements of 10 CFR §19.12, individuals must be instructed in the operating procedures applicable to work under the license and must be required to demonstrate familiarity with precautions, procedures, and devices included in the instructions.
- (3) Records documenting individual worker instruction shall be maintained for inspection by the Department for a period of 3 years.
- (4) Each licensee must inform each worker annually of the worker’s exposure to radiation or radioactive material as shown in the records maintained by the licensee pursuant to 10 CFR §20.2106.

**§175.102 Standards for protection against radiation.**

- (a) Except as set forth in subdivision (b) of this section, 10 CFR Part 20 is hereby incorporated by reference herein to this Article with the same force and effect as if fully set forth in its entirety.
- (b) The following provisions from 10 CFR Part 20 are not so incorporated: §20.1001, §20.1002, §§20.1006 through 20.1009, §20.1406(b), §20.1905(g), §20.2203(c), §20.2206, §20.2401, §20.2402 and Part 20 Appendix D.
- (c) Additional requirements.
- (1) Radiation protection programs.
- (i) Each licensee must:
- (A) provide a radiation safety officer pursuant to 10 CFR §§35.24 and 35.50 who shall be delegated authority to ensure the implementation of this radiation protection program and ensure radiation doses are As Low As Reasonably Achievable (ALARA) (as defined in 10 CFR §20.1003 and more fully described in §175.105(c)(1)). The radiation safety officer or associate radiation safety officer named on the license, or an authorized user designated to act as the radiation safety officer in the radiation safety officer's absence, must be present on the premises at least 50 percent of the time that radioactive material is being handled or equipment containing radioactive material is being operated;
- (B) provide for a radiation safety committee to administer the radiation protection program in medical centers, hospitals and institutions of higher education. The committee must include the facility operator or a person with the authority to act on behalf of the facility operator, and representation from departments within the facility where radiation sources are used. The committee must meet at least quarterly and must oversee all uses of radioactive materials within the facility, must review the activities of the radiation safety officer, and must review the radiation safety program at least annually. The committee, or a subcommittee, must oversee the administration of a quality assurance program as required by §175.108;
- (C) provide a quality assurance program for diagnostic and therapeutic uses of radioactive materials pursuant to §175.108 and other applicable provisions of this Article; and

- (D) ensure that all personnel involved in planning for, or administering radiation doses to humans, or in the use of radioactive materials for other lawful purposes, are supervised, are instructed as described in 10 CFR §19.12 and are competent to safely use such radiation sources and services.
  - (ii) For non-human use radioactive materials installations, the radiation safety officer specified in §175.102(c)(1)(i)(A) must be:
    - (A) a physicist certified by the American Board of Health Physics, the American Board of Radiology or the American Board of Medical Physics in a branch of physics related to the type and use of radioactive material in the installation; or
    - (B) a person with equivalent training and experience as determined by the Department; or
    - (C) an authorized user named on the radioactive materials license issued by the Department.
- (2) Individual monitoring.
- (i) In addition to the criteria in 10 CFR §20.1502(a)(2),(3), each licensee must monitor occupational exposure for minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a deep dose equivalent in excess of 10 percent of any of the applicable limits in 10 CFR §§20.1201 or 20.1208.
  - (ii) A person supplying personnel monitoring devices to individuals pursuant to 10 CFR §20.1502 must ensure that the individuals wear such devices as follows:
    - (A) An individual monitoring device used for monitoring the dose to the whole body must be worn at the unshielded location of the whole body likely to receive the highest exposure, except when monitoring is performed in accordance with §175.17(b)(4).
    - (B) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant worker pursuant to 10 CFR §20.1208 must be located at the waist under any protective garment worn by the declared pregnant worker.
    - (C) An individual monitoring device used for monitoring the lens dose equivalent must be located at the neck outside any protective garment worn by the individual, or at an unshielded location closer to the eye.
    - (D) An individual monitoring device used for monitoring the dose to the extremities must be worn on the extremity likely to receive the highest exposure. The device must be oriented to measure the highest dose to the extremity being monitored.
  - (iii) The licensee must ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device, and no licensee must remove an exposure from an individual's exposure record without prior authorization from the Department. The licensee must submit the dosimeter for processing with due diligence and in no event in excess of the time period specified by the manufacturer of the dosimeter.
- (3) Respiratory protection.
- (i) If the licensee uses respiratory protection equipment to limit intakes pursuant to 10 CFR §§20.1701 through 20.1705, the licensee must issue a written policy statement on respirator usage covering:
    - (A) the routine, non-routine, and emergency use of respirators; and
    - (B) limitations on periods of respirator use and relief from respirator use; and
    - (C) the use of process or other engineering controls, instead of respirators.
  - (ii) For a licensee to make allowance for respiratory equipment when estimating the exposure of individuals to airborne radioactive material, the following additional condition applies: the licensee selects respiratory protection equipment that provides a protection factor, specified in 10 CFR Part 20 Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Table 1, Column 3 of 10 CFR Part 20 Appendix A. However, if the selection of respiratory protection equipment with a protection factor greater than this multiple of peak concentration is inconsistent with the goal specified in 10 CFR §20.1702 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower

- protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the initially estimated dose, the corrected value must be used. If the dose is later found to be less than the initially estimated dose, the corrected value may be used.
- (4) Requirements for possession of sealed sources.
- (i) The licensee in possession of any sealed source must follow the radiation safety and leak testing requirements specified in 10 CFR §35.67.
  - (ii) Reports of test results for leaking or contaminated sealed sources must be made pursuant to 10 CFR §35.3067.
  - (iii) A licensee authorized for medical use in possession of a licensed sealed source or brachytherapy source must survey with a radiation survey instrument at intervals not to exceed 3 months all areas where such sources are stored. This shall not apply to sources in teletherapy units or gamma stereotactic radiosurgery units or to sealed sources in diagnostic devices.
- (5) Radioactive material must not be stored with either food or beverages.
- (6) No person shall bury any licensed radioactive material within New York City.
- (7) The provisions of 10 CFR §20.2005 do not authorize the licensed materials described to be disposed of inside the City as if they were not radioactive; however, these materials may be shipped for disposal outside of the City as if they were not radioactive provided that the receiving jurisdiction allows the disposal of such materials as if they were not radioactive.
- (8) Vacating premises. Each specific licensee must notify the Department in writing of intent to vacate not less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of licensed activities. When deemed necessary by the Department, the licensee must decontaminate the premises to such levels as the Department may specify.
- (9) Recordkeeping requirements for receipt, use, and disposition of radioactive material.
- (i) Each licensee must maintain records of the receipt, use, and disposition of radioactive material in units of becquerels or microcuries and must include from whom such materials were received and the ultimate disposition.
  - (ii) The licensee must retain these records for 3 years after the record is made.
- (10) The Department may order the removal, through an authorized person, or the surrender to the Department, of any radiation source by any person who:
- (i) does not hold, or continue to hold, a valid license issued by the Department; or
  - (ii) is not able or equipped, or who fails to observe with regard to such radiation source, those radiation protection standards established or enforced by the Department or who uses such radiation source in violation of law, regulation, this Article, order or license issued by the Department. Such person must decontaminate any premises which may have been contaminated with radioactive material as a result of any such activities to such radiation levels as the Department may specify. The expenses incidental to such transfer, surrender, and decontamination must be borne by such person responsible for the source.
- (11) In determining the extent of any individual's exposure to radiation subsequent to any radiation accident, contamination, theft or loss, the licensee must comply with all orders of the Department directing such licensee to make available to such individual appropriate medical evaluation services or appropriate tests and to furnish a copy of the reports of such evaluation or test to the Department.
- (12) A licensee or applicant for a license must obtain any permits required by the New York State Department of Environmental Conservation pursuant to 6 NYCRR Part 380, or any successor law

or regulation, and must develop, document, and implement a discharge minimization program required by the New York State Department of Environmental Conservation pursuant to 6 NYCRR §380-7, or any successor law or regulation.

**§175.103 General requirements for radioactive materials.**

- (a) Except for the removal of source material from its place of origin in nature, or as otherwise may be provided in this Article, no person subject to this Article shall transfer, receive, produce, possess or use in New York City any radioactive material except pursuant to a license issued by the Department.
- (b) Except as set forth in subdivision (c) of this section, 10 CFR Part 30 and the following provisions from 10 CFR Part 40: §40.3, the definition of "byproduct material and "depleted uranium" in §40.4 §40.11, §40.12(a), §40.13 (except §40.13(c)(5)(iv)), §40.21, §40.22, §40.41(a)-(c),(f), §§40.42 (c)-(k)(3),(l), §40.46, §40.51 (except 40.51(b)(6)), §40.54, §40.55, §40.60 and §40.61 are hereby incorporated by reference herein to this Article with the same force and effect as if fully set forth in their entirety.
- (c) The following provisions from 10 CFR Parts 30 are not so incorporated: §30.1, §30.2, the definitions of "commencement of construction" and "construction" in §30.4, §§30.5 through 30.8, §30.21(c), §30.32(e), §30.34(d), §30.34(e)(1), §30.34(e)(3), §30.36 (d)-(k), §§30.37 through 30.39, §30.41(b)(6), §30.53, 30.55, §30.62, §30.63 and §30.64 .
- (d) References to "Department" in the incorporated regulations of 10 CFR §§30.12 and 30.41(b)(1) means the U.S. Department of Energy.
- (e) Any reference to "byproduct material" in the incorporated regulations of 10 CFR §§30.31 through 30.62 means "radioactive material" as defined in this Article.
- (f) Additional requirements.
  - (1) License termination requirements.
    - (i) If a licensee does not submit an application for renewal of a radioactive materials license pursuant to 10 CFR §30.32, then the licensee must, on or before the expiration date stated in the license.:
      - (A) Terminate use of radioactive material;
      - (B) Dispose of all radioactive material in accordance with all applicable regulations in effect at the time of disposal;
      - (C) Submit a written certification of the disposition of all radioactive materials authorized by the license on forms prescribed by the Department;
      - (D) Remove radioactive contamination to the extent practicable; and
      - (E) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a copy of this survey to the Department. Such survey must be subject to approval by the Department and must include:
        - (a) Levels of radiation in units (or multiples) of Gy-hr-1 (millirads-hr-1) at 1 cm for beta-gamma radiation or at 1 m for gamma radiation;
        - (b) Levels of removable and fixed contamination, including alpha, in units of disintegrations (transformations) per min (becquerels) per 100 cm<sup>2</sup> for surfaces;
        - (c) becquerels-ml<sup>-1</sup> (mCi-ml<sup>-1</sup>) for water;
        - (d) becquerels-kg<sup>-1</sup> (pCi-g<sup>-1</sup>) for solids such as soil or concrete; and
        - (e) a description of the survey or other measuring instruments used, including manufacturer and model numbers and date of most recent calibration.
    - (F) If the information submitted pursuant to clauses (A) through (E) of subparagraph (i) of paragraph (1) of subdivision (f) of this section does not adequately demonstrate that the premises are suitable for unrestricted use, the Department shall inform the licensee of the appropriate further actions required for the termination of the license, including, but not limited to, decontamination of the licensed premises to such levels and within such time frames as the Department may prescribe.
  - (ii) Each specific license shall continue in effect, beyond the expiration date if necessary, with

- respect to the presence of any residual radioactive materials that may be present as contamination until the Department terminates the license. During this time, the licensee must:
- (A) Limit activities involving radioactive material to those related to decommissioning; and
  - (B) Continue to control entry to restricted areas until the Department determines they are suitable for release for unrestricted use and the Department terminates the license.
- (iii) The Department can terminate a specific license when the Department determines that:
- (A) All licensed radioactive material has been properly transferred or disposed; and
  - (B) premises have been decontaminated to such levels that the total effective dose equivalent (TEDE) from residual radioactivity distinguishable from background radiation, to an average member of the public will not exceed 25 mrem (0.25 mSv) per year;
  - (C) a radiation survey has been performed which describes all radiation levels and levels of fixed and removable contamination; and
  - (D) the licensee submits sufficient documentation to support a determination that the requirements of clauses (A) through (E) of subparagraph (i) of paragraph (1) of subdivision (f) of this section have been met.
- (2) Amendment of licenses by the Department.
- (i) A corrective amendment of any license may be issued by the Department at any time upon its initiative.
  - (ii) Any license may be amended or revoked by the Department by reason of the amendment of this Article, or any other applicable law.
- (3) The licensee must notify the Department, in writing, within 30 days if an authorized user, radiation safety officer or radiation therapy physicist permanently discontinues performance of duties under the license.
- (4) No person, in any advertisement or public posting, expressly or by implication, shall refer to the fact that a radiation installation is licensed by the Department, and no person shall state or imply that a radiation installation or its activities have been approved by the Department, the Board of Health or the Commissioner.
- (5) Reciprocity. The holder of a license issued by the New York State Department of Environmental Conservation, the New York State Department of Health, the U.S. Nuclear Regulatory Commission or any Agreement State, may bring, possess or use radioactive material covered by such license within the Department's jurisdiction for a period not in excess of 30 days in any 12 consecutive months without obtaining a license from the Department, provided that:
- (i) such license does not limit the holder's possession or use of such material to a specific installation or installations;
  - (ii) such holder, prior to bringing such material into the City, files with the Department a notice indicating the period, type and location of proposed possession and use within the Department's jurisdiction, and a copy of the license;
  - (iii) such holder supplies such additional information as the Department may reasonably request;
  - (iv) such holder, during the period of this possession and use of such material within the City, complies with all applicable sections of this Article except §175.103(a); and
  - (v) such holder, during such period, complies with all the terms and conditions of his license, except if any such license terms or conditions are determined by the Department to be inconsistent with the requirements of this Article.
- (6) If the holder of a license issued by this Department, the New York State Department of Environmental Conservation, the New York State Department of Health, or an Agreement State intends to conduct any licensed activity in areas of exclusive federal jurisdiction within New York City, then before engaging in any such licensed activity for the first time in a calendar year, such licensee must provide the U.S. Nuclear Regulatory Commission with at least 3 days advanced notice of its proposed activity in such areas under exclusive federal jurisdiction within New York City.

**§175.104 Specific types of radioactive materials licenses.**

- (a) Types of license. The requirements specified in this section are in addition to, and not in substitution for, others in this Article. In particular, the incorporated provisions of 10 CFR Part 30 apply to all license applications and all specific radioactive materials licenses. For the purposes of this Article, the following specific license types of radioactive materials apply:
- (1) A specific license of limited scope for gamma stereotactic radiosurgery (GSR) or for teletherapy means a license that authorizes receipt, acquisition, ownership, possession, use and transfer of specified quantities and types of radioactive material for use in GSR or teletherapy programs.
  - (2) A specific license of limited scope for medical use means a license that authorizes receipt, acquisition, ownership, possession, use and transfer of specified quantities and types of radioactive material for use in or on humans in a medical program, but does not include GSR or teletherapy.
  - (3) A specific license of limited scope for other use means a license that authorizes receipt, production, acquisition, ownership, possession, use and transfer of specified quantities and types of radioactive material for uses other than in or on humans.
  - (4) A specific license of broad scope for medical use means a license that authorizes receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive materials specified in the license, for use in or on humans in a medical program, but does not include GSR or teletherapy.
  - (5) A specific license of broad scope for research and development means a license that authorizes receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive materials specified in the license, in quantities not exceeding those specified in the license, for uses other than in or on humans.
- (b) Specific licenses for human use of radioactive materials in institutions. An application by a medical institution for a specific license for medical use of radioactive material may be approved if:
- (1) pursuant to §§175.103 and 175.105, the applicant satisfies the requirements specified in the incorporated provisions of 10 CFR Parts 30 and 35; and
  - (2) the applicant possesses adequate facilities for the clinical care of patients; and
  - (3) the physician designated on the application as the individual authorized user has training and experience as specified in 10 CFR Part 35, in the proposed use, handling and administration of radionuclides and the clinical management of radioactive patients. The physician must furnish evidence of such experience with the application. A statement from the physician's preceptor at the medical institution where the physician acquired such training and experience, indicating their amount and nature, may be submitted as evidence of such experience.
  - (4) The license application is signed by the chairman of the radiation safety committee and an authorized representative of the medical institution.
- (c) Specific licenses to individual physicians for human use of radioactive materials. An application by an individual physician for a specific license for human use of radioactive material may be approved if:
- (1) pursuant to §§175.103 and 175., the applicant satisfies the requirements specified in the incorporated provisions of 10 CFR Parts 30 and 35; and
  - (2) the applicant has training and experience as specified in 10 CFR Part 35 in the proposed use, handling and administration of radionuclides, and the clinical management of radioactive patients. The physician must furnish evidence of such training and experience with the application. A statement from the physician's preceptor at the institution where the physician acquired such training and experience, indicating their amount and nature, may be submitted as evidence of such experience.
- (d) Specific licenses of broad scope.
- (1) A specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of the byproduct material specified in the license, but not exceeding quantities specified in the license. Approved authorized users do

- not need to be listed on the license. Specific licenses of broad scope for medical use are exempted from certain requirements as listed in 10 CFR §35.15.
- (2) A specific license of broad scope shall be issued only to medical institutions, research laboratories, or institutions of higher education; such licenses shall not be issued to individuals.
- (3) An application for a specific license of broad scope may be approved if:
- (i) the applicant satisfies the general requirements specified in 10 CFR §30.33; and
  - (ii) the applicant has engaged in a reasonable number of activities involving the use of radioactive material as determined by the Department; and
  - (iii) the applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:
    - (A) the establishment of a radiation safety committee pursuant to §175.102(c)(1)(i)(B); and
    - (B) the appointment of a full-time radiation safety officer pursuant to 10 CFR Part 20; and
    - (C) the establishment of appropriate administrative procedures to assure:
      - (a) control of procurement and use of radioactive material; and
      - (b) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
      - (c) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with §175.104(d)(3)(iii)(C)(b) prior to the use of radioactive materials.
- (4) The following are conditions of all specific licenses of broad scope. Unless specifically authorized pursuant to other provisions of this Article, broad scope licensees must not:
- (i) conduct tracer studies in the environment involving direct release of radioactive material;
  - (ii) receive, acquire, own, possess, use, transfer, or import devices containing 3.7 E6 GBq (100,000 Ci) or more of radioactive material in sealed sources used for irradiation of materials;
  - (iii) add, or cause the addition of, radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion by, or application to, a human being except as authorized in the license.
- (e) Specific licenses for non-human use. An application for a specific license authorizing non-human use of radioactive materials may be approved if:
- (1) the applicant satisfies the general requirements specified in 10 CFR §30.33; and
  - (2) the applicant, or the applicant's personnel, has training and experience commensurate with the proposed amounts, types and uses of radioactive materials which must minimally include:
    - (i) a college degree at the bachelor level in a physical, biological, environmental or engineering science; and
    - (ii) at least 40 hours of training and experience in the safe handling of radioactive materials appropriate to the type and forms of such materials to be used, which must include:
      - (A) characteristics of ionizing radiation;
      - (B) units of radiation dose and quantities;
      - (C) radiation detection instrumentation; and
      - (D) biological hazards of exposure to radiation.
- (f) General licenses.
- (1) Except as set forth in paragraph (2) of this subdivision, 10 CFR Part 31 is hereby incorporated by reference herein to this Article with the same force and effect as if fully set forth in its entirety.
  - (2) The following provisions from 10 CFR Part 31 are not incorporated: §31.1, §31.2, §31.4, §31.22 and §31.23.
  - (3) Any reference to "byproduct material" in the incorporated 10 CFR §31.9 means "radioactive material" as defined in this Article.
  - (4) Reference to "non-Agreement State" in the incorporated 10 CFR §31.6 means this Department.

(5) Licensees exempt pursuant to incorporated 10 CFR §31.12(b) are similarly exempt from the analogous license requirements of this Article.

**§175.105 Medical use of radioactive materials.**

(a) Except as set forth in subdivision (b) of this section, 10 CFR Part 35 is hereby incorporated by reference herein to this Article with the same force and effect as if fully set forth in its entirety.

(b) The following provisions from 10 CFR Part 35 are not so incorporated: §35.1, §35.8, §35.11(c)(1), §35.13(a)(1), §35.4001 and §35.4002.

(c) Additional requirements.

(1) ALARA program.

(i) Each licensee must develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas to be As Low As Reasonably Achievable (ALARA) in accordance with this subdivision.

(ii) To satisfy the requirement of subparagraph (i) of this paragraph (1):

(A) for licensees that are medical institutions, the management, radiation safety officer and all authorized users must participate in the establishment, implementation, and operation of the program as required by this Article or required by the radiation safety committee; or

(B) for licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the radiation safety officer.

(iii) The ALARA program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA.

(iv) For licensees that are medical institutions, the ALARA program must include an annual review by the radiation safety committee as indicated in paragraph (1) of subdivision (c) of §175.102.

(v) For licensees that are not medical institutions, the ALARA program must include an annual management review of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material, prepared by all authorized users or the radiation safety officer.

(vi) The purpose of the review required by subparagraphs (iv) and (v) of this paragraph (1) is to ensure that every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material to unrestricted areas, are ALARA, taking into account the state of technology and the cost of improvements in relation to benefits.

(vii) The licensee must retain a current written description of their ALARA program for the duration of the license. The written description must include:

(A) a commitment by management to keep occupational doses as low as reasonably achievable;

(B) a requirement that the radiation safety officer brief management at least once each year on the radiation safety program; personnel exposure investigational levels that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure (ALARA I); and personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might to be taken to reduce the probability of recurrence (ALARA II).

(2) Qualified personnel. Personnel, duly licensed by the New York State Department of Health to practice nuclear medicine technology (other than physicians or registered professional nurses), at licensee locations involved in the performance of diagnostic procedures utilizing radioactive material, which includes parenteral administration of radioactive material by intravenous, intramuscular or subcutaneous methods, must:

(i) have satisfactorily completed an educational program in nuclear medicine technology accredited by the Committee on Allied Health Education and Accreditation, or the accrediting agency of the state in which the program was completed, provided such state accreditation requires education and training in the above methods of parenteral administration; or



- (ii) possess certification as a nuclear medicine technologist by the American Registry of Radiologic Technologists or certification by the Nuclear Medicine Technology Board; and
- (iii) prior to permitting parenteral administration by a nuclear medicine technologist, the medical board of a hospital, a physician, or the radiation safety committee of an institution who have no medical board, must adopt with governing authority approval:
  - (A) procedures to assure that the nuclear medicine technologist possesses the education and training or certification set forth in this subdivision and is proficient in the competent performance of parenteral administration; and
  - (B) requirements for authorized user physician, which at a minimum must require supervision by such physician when parenteral administration of radioactive material for diagnostic testing is performed by a qualified nuclear medicine technologist.
- (iv) The requirements of this paragraph concerning qualified personnel are in addition to, and not in place of, any other requirements in this Article or in the incorporated 10 CFR sections relating to supervision or the presence of an authorized user.
- (3) *Possession, use, calibration and check of dose calibrators.*
  - (i) A medical use licensee authorized to administer radioactive materials must possess a dose calibrator and use it to measure the amount of activity administered to each patient.
  - (ii) A licensee must:
    - (A) check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy this requirement, the check must be done on a frequently used setting with a sealed source of any photon-emitting radionuclide with a half-life greater than 90 days;
    - (B) test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources of appropriate source activity, containing different radionuclides, the activity of which the manufacturer has determined by traceability to a national standard to be within 5 percent of the stated activity;
    - (C) test each dose calibrator for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use between 1 MBq (27  $\mu$ Ci) and the highest dosage that will be administered; and
    - (D) test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee must keep a record of this test for the duration of the use of the dose calibrator.
  - (iii) Notwithstanding the provisions of subparagraph (ii) of paragraph (3) of this subdivision, a licensee that uses a dose calibrator to measure the activity of beta- emitting radioactive materials to be administered to a patient must perform additional checks specified in clauses (A) and (B) of subparagraph (ii) of paragraph (3) of this subdivision using the same radionuclide to be administered and having an activity of at least 50 percent, but not more than 200 percent, of the prescribed activity or by equivalent procedures approved by the Department. Records must be kept pursuant to §175.105(c)(3)(vi).
  - (iv) A licensee must mathematically correct dosage readings for any geometry or linearity error that exceeds  $\pm 10$  percent if the dosage is greater than 370 kBq (10 $\mu$ Ci) and must repair or replace the dose calibrator if the accuracy or constancy error exceeds  $\pm 10$  percent.
  - (v) A licensee must also perform checks and tests required by §175.103(c)(3)(ii) following adjustment or repair of the dose calibrator.
  - (vi) A licensee must retain a record of each check and test required by subparagraphs (ii), (iii) and (v) of §175.105(c)(3) for 3 years. Such records must include:
    - (A) for clause (A) of §175.105(c)(3)(ii), the models and serial numbers of the dose calibrator and check source, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the name of the individual who performed the check;
    - (B) for clause (B) of §175.105(c)(3)(ii), the model and serial number of the dose calibrator, the

- model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, proof of traceability to a national standard, the date of the test, the results of the test, the instrument settings, and the signature of the radiation safety officer;
- (C) for clause (C) of §175.105(c)(3)(ii), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the radiation safety officer; and
- (D) for clause (D) of §175.105(c)(3)(ii), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the radiation safety officer.
- (4) *Possession and calibration of portable survey instruments.*
- (i) A licensee authorized to use radioactive material for any medical use permitted in 10 CFR §§35.100, 35.200, 35.300, 35.400, 35.500, or 35.600 must have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 1.0  $\mu$ Sv (0.1 mrem) per hour to 1000  $\mu$ Sv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10  $\mu$ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. This requirement may be met by possession of two survey instruments or by possession of one survey instrument that meets both criteria. The instruments must be operable and calibrated in accordance with 10 CFR §35.61.
- (ii) To meet the requirements of §175.105(c)(4)(i), the licensee must perform such calibrations as authorized by specific license condition, or must obtain the services of persons licensed by the U.S. Nuclear Regulatory Commission or an agreement state to perform calibrations of survey instruments.
- (iii) A licensee must check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.
- (5) *Surveys of exposure rate and contamination.* In addition to the requirements of 10 CFR §35.70, a licensee must:
- (i) survey with a radiation detection survey instrument at least once each week all areas where unsealed byproduct materials or radioactive wastes are stored;
- (ii) conduct the surveys required by 10 CFR §35.70 and §175.105(c)(5)(i) so as to be able to detect and measure dose rates as low as 1  $\mu$ Sv (0.1 mrem) per hour.
- (iii) establish dose rate action levels for the surveys required by 10 CFR §35.70 and §175.103(c)(5)(i) and must require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.
- (iv) perform wipe tests for removable contamination once each week on all areas where radioactive materials are routinely prepared for use or administered and where unsealed sources of radioactive materials are stored, so as to be able to detect contamination on each wipe sample of 35 Bq (2100 disintegrations or transformations per minute).
- (v) establish removable contamination action levels for the surveys required by §175.105(c)(5)(iv) and must require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.
- (vi) retain a record of each survey or wipe test required by 10 CFR §35.70 and §175.105(c)(5) for 3 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in Sv (mrem) per hour or the removable contamination in each area expressed in becquerels (disintegrations or transformations per minute) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.
- (6) *Additional requirements for use of generators aerosols, gases, and volatile materials.*
- (i) A licensee approved to use unsealed byproduct material for medical use permitted in 10 CFR

- §35 Subpart D may use generators, radioactive aerosols, or radioactive gases only if specific application is made to and approved by the Department.
- (ii) Storage of volatiles and gases.
- (A) A licensee must store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.
- (B) After drawing the first dosage, a licensee must store and use a multidose container in a properly functioning fume hood.
- (iii) Control of aerosols and gases.
- (A) A licensee who administers radioactive aerosols or gases must do so with a system that will keep airborne concentrations within the limits prescribed by 10 CFR Part 20.
- (B) The system must provide for collection and decay or disposal of the unused aerosol or gas in a shielded container.
- (C) Before receiving, producing, using, or storing a radioactive gas, the licensee must calculate the amount of time needed after a release to reduce the concentration in the area of use to the ALI listed in Table 1 of Appendix A of 10 CFR Part 20. The calculation must be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.
- (D) A licensee must post the time calculated in §175.105(c)(6)(iii)(C) at the area of use, as well as safety measures to be instituted in case of a spill at the area of use.
- (E) A licensee must check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements must be maintained for 3 years.
- (F) A copy of the calculations, including assumptions, measurements and calculations made, required in §175.105(c)(6)(iii)(C) must be recorded and retained for the duration of the license.
- (7) Radioactive cadavers.
- (i) If any patient containing radioactive material administered/implanted for therapeutic purposes dies, the physician who pronounces such patient as dead must notify immediately the physician in charge of the case or such physician's designated representative.
- (ii) No person shall commence any autopsy on any cadaver that contains more than 185 MBq (5 mCi) of radioactive material administered/implanted for therapeutic purposes without first having consulted with, and having been advised by, the radiation safety officer of the hospital or the physician responsible for the administration/implantation of the radioactive material. If neither is available, a designated representative may serve.
- (iii) A radioactivity report on every cadaver containing more than 185 MBq (5 mCi) of radioactive material administered/implanted for therapeutic purposes must be completed by the radiation safety officer or the physician responsible for the administration of the radioactive material or their designated representative. The report must include the name, address and radioactive materials license number of the hospital; the name of the deceased; the name, address and telephone number of the next of kin; the name, address and telephone number of the funeral home to which the deceased will be sent; the radionuclide involved; the approximate activity on the date of the report and the physical form; the location of the radioactive materials within the body and the external dose rate at the body surface closest to the source; the precautions to be observed during autopsy or handling of the body by the funeral director; and the name of the person who prepared the form. This report must accompany the body, whether autopsied or not, when it is surrendered to the funeral director. The Department must be notified in person, by telephone, or by facsimile within 24 hours of the death and a copy of the radioactivity report must be sent to the Department within 15 days of the date of death.
- (8) Safety requirements for uses authorized in 10 CFR §35 Subparts E and F.
- For each patient or research subject who cannot be released pursuant to 10 CFR §35.75, a licensee must:
- (i) authorize visits by individuals under age 18 only on a patient-by-patient basis with the

- approval of the authorized user after consultation with the radiation safety officer.
- (ii) promptly after implanting the dosage or sources, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20 and retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in mSv (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey.
- (9) Additional requirements for uses authorized in 10 CFR §35 Subpart H.
  - (i) Amendment requests. In addition to the requirements specified in 10 CFR §35.13, a licensee must apply for and have received a license amendment prior to:
    - (A) making any change in the treatment room shielding;
    - (B) making any change in the location of a gamma stereotactic radiosurgery (GSR) unit or a teletherapy unit within the treatment room;
    - (C) using the GSR or teletherapy unit in a manner that could result in increased radiation levels in areas outside the treatment room;
    - (D) relocating the GSR or teletherapy unit; or
    - (E) allowing an individual not listed on the licensee's license to perform the duties of the authorized medical physicist.
  - (ii) A licensee must furnish a copy of the records required in 10 CFR §§35.632 and 35.635 and the output from the teletherapy source expressed as Sv (rem) per hour at one meter from the source determined during the surveys required in 10 CFR §35.652 to the Department within 30 days following completion of the action that initiated the record requirement.
  - (iii) Modification of a GSR or teletherapy unit or room before beginning a treatment program. If the survey required by 10 CFR §35.652 or §175.105(c)(9)(iv) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 10 CFR Part 20, before beginning the treatment program, the licensee must:
    - (A) either equip the unit with stops or add additional radiation shielding to ensure compliance with 10 CFR Part 20;
    - (B) perform the survey required by 10 CFR §35.652 again; and
    - (C) include in the report required by §175.105(c)(9)(ii), the results of the initial survey, a description of the modification made to comply with 10 CFR §35.652(a) and the results of the second survey; or
    - (D) request and receive a license amendment that authorizes radiation levels in unrestricted areas greater than those permitted by 10 CFR Part 20.
- (10) Records.
  - (i) In lieu of the retention requirements of 10 CFR §35.2067, records of leak tests required by 10 CFR §35.67(b) and the semi-annual physical inventory of sealed sources and brachytherapy sources required by 10 CFR §35.67(g) shall be retained for 5 years.
  - (ii) In addition to the requirements of 10 CFR §35.2630, for each intercomparison, the record must include evidence that the intercomparison reading was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.
- (11) Visiting authorized user. Notwithstanding other provisions of this Article, a licensee may permit any physician to act as a visiting authorized user under the term of the license for up to 60 days per calendar year if:
  - (i) the visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee (where applicable); and
  - (ii) the visiting authorized is specifically named as a user on a license issued by the Department, Nuclear Regulatory Commission, or an Agreement State, and only performs procedures for

- which they are specifically authorized on that license, and  
(iii) the licensee maintains copies of the written permission required by subparagraph (i) of this paragraph and documentation that the visiting authorized user met the requirements of subparagraph (ii) of this paragraph for 5 years from the date of the last visit.

**§175.106 Transportation and packaging of radioactive materials.**

- (a) Except as set forth in subdivision (b) of this section, 10 CFR Part 71 is hereby incorporated by reference herein to this Article with the same force and effect as if fully set forth in its entirety.  
(b) The following provisions from 10 CFR Part 71 are not so incorporated: §71.2, §71.6, §71.11, §71.14(b), §71.19, §§71.31 through 71.45, §§71.51 through 71.77, §71.85(a)-(c), §71.91(b), §71.99, §71.100, §71.101(c)(2), §71.101(d)-(f), §71.107 through §71.125.  
(c) Licensees must ascertain that the certificate holder determinations in subsections (a) through (c) of 10 CFR §71.85 have been made.  
(d) The requirements of the incorporated 10 CFR §§71.106 and 71.135 apply to general licensees and do not apply to certificate of compliance holders or applicants for certificates of compliance as those terms are defined in 10 CFR §71.4.  
(e) A licensee's quality assurance program referenced in the incorporated 10 CFR Part 71 Subpart H regulations as to packaging must be submitted to the Department at the address provided in §175.01(c).  
(f) Transport authorized by the incorporated 10 CFR §71.13 must not be by public modes of transportation including, but not limited to, buses, subways, trams, taxicabs, car services, trains, ferries, or other public conveyance, which would be returned immediately to public use after transporting licensed material.

**§175.107 Physical protection of category 1 and category 2 quantities of radioactive material.**

- (a) Except as set forth in subdivision (b) of this section, 10 CFR Part 37 is hereby incorporated by reference herein to this Article with the same force and effect as if fully set forth in its entirety.  
(b) The following provisions from 10 CFR Part 37 are not so incorporated: §37.1, §37.3, §37.7, §37.9, §37.11(a-b), § 37.13, §37.105, §37.107 and §37.109.

**§175.108 Quality assurance programs.**

- (a) Purpose and scope. This section establishes requirements for the use of radioactive materials or the radiation therefrom for diagnostic and therapeutic uses in the healing arts. These requirements provide for the protection of the public health and safety and are in addition to, and not in substitution for, other requirements in this Article. The requirements of this section apply to all licensees subject to this Article.  
(b) Diagnostic facilities. A quality assurance program is a system of plans, actions, reviews, reports and records, the purpose of which is to ensure that diagnostic facilities achieve consistent high quality imaging and other diagnostic results, while maintaining personnel doses within limits prescribed by the Department.  
(1) Each licensee performing diagnostic procedures must implement a quality assurance program, which includes at a minimum:  
(i) the adoption of a manual containing written policies and procedures for radiation protection and describing the licensee's quality assurance program that is facility- and equipment-specific. Policies and processes must be consistent with the types of procedures provided including, but not limited to, identification of patients, personnel monitoring, and protection of pregnant workers and patients. The quality assurance manual must describe the various processing, generator and systems quality control tests appropriate for the types of procedures provided in sufficient detail to ensure that they will be performed properly;  
(ii) the performance of quality control tests and the correction of deficiencies as specified in the quality assurance manual;

- (iii) the provisions of a formalized in-service training program for employees including, but not limited to, quality assurance and radiation safety procedures;
- (iv) the measurement of the amount of activity of each dose of a radiopharmaceutical/ radiobiologic administered to each patient;
- (v) the provision of the information described in §175.108(b)(1)(iv) to any patient upon request; and
- (vi) the performance of an ongoing program of analysis of repeated, rejected or wrongly administered diagnostic studies which are designed to identify and correct problems and to optimize quality.
- (2) Each licensee must maintain written records documenting quality assurance and audit activities for review by the Department. Unless otherwise required, such records must be maintained by the licensee until after the next scheduled inspection is completed by the Department.
- (c) External beam and brachytherapy. A quality assurance program for external beam therapy or brachytherapy is a system of plans, actions, reviews, reports and records, the purpose of which is to ensure a consistent and safe fulfillment of the dose prescription to the target volume with minimal dose to normal tissue.
  - (1) Each licensee authorized to administer external beam therapy or brachytherapy to humans must implement a quality assurance program to systematically monitor, evaluate and document radiation therapy services to ensure consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissue, minimal exposure to personnel and adequate patient monitoring aimed at determining the end result of the treatment. Each licensee must meet or exceed all quality assurance criteria described in this subdivision.
  - (2) Each licensee must adopt and maintain a quality assurance program that includes policies and procedures that require the following:
    - (i) Each patient's medical record must be complete, accurate, legible and must include the patient's initial clinical evaluation, treatment planning data, treatment execution data, clinical assessments during treatment, a treatment summary and plan for subsequent care. Treatment related data must be recorded in the patient's medical record at the time of each treatment.
    - (ii) A written directive or dated order or prescription for the medical use of radiation or radioactive material must be made for each patient in accordance with 10 CFR §35.40. The directive, order or prescription must be signed or approved electronically by a board certified radiation oncologist or qualified physician who restricts their practice to radiation oncology.
    - (iii) The accuracy of treatment plan data and any modifications to treatment plan data transferred to a radiation treatment delivery system must be verified by qualified clinical staff prior to patient treatment.
    - (iv) A radiation therapy technologist, physician or other qualified health practitioner must verify that the patient set up on the treatment machine is in accordance with the treatment plan prior to the first fraction of a course of treatment and prior to treatment for any changes to the initial treatment plan.
    - (v) Clinical staff must obtain clarification before beginning a patient's treatment if any element of the order or other record is confusing, ambiguous, erroneous or suspected of being erroneous.
    - (vi) Each patient's identification must be verified by at least two different means by qualified clinical staff prior to each treatment.
    - (vii) Each patient's response to treatment must be assessed by a board certified radiation oncologist or other qualified physician in the active practice of external beam therapy or brachytherapy. Unusual responses must be evaluated as possible indications of treatment errors and recorded in the patient's medical record.
    - (viii) The medical records of patients undergoing fractionated treatment must be checked for completeness and accuracy by qualified clinical staff at intervals not to exceed six fractions.
    - (ix) Radiation treatment plans and related calculations must be checked by qualified clinical staff for accuracy before 25 percent of the prescribed dose for external beam therapy or 50 percent

- of the prescribed dose for brachytherapy is administered, except the check must be performed prior to treatment for: any single fraction treatment; any fractional dose that exceeds 300cGy or 700 monitor units; or when the output of a medical therapy accelerator exceeds 600 monitor units per minute during treatment. If a treatment plan and related calculations were originally prepared by a board certified radiation oncologist or an authorized medical physicist possessing the qualifications specified in 10 CFR §35.51, it may be rechecked by the same individual using a different calculation method. Treatment plans and related calculations prepared by other qualified clinical personnel must be checked by a second qualified person using procedures specified in the treatment planning procedures manual required pursuant to paragraph (3) of this subdivision and who has received training in use of this manual.
- (x) All equipment and other technology used in planning and administering radiation therapy must function properly and safely, and must be calibrated properly and repaired and maintained in accordance with the manufacturer's instructions. The equipment and technology that is subject to such quality control, includes but is not limited to: computer software and hardware including upgrades and new releases; equipment used to perform simulation; dosimetry equipment; equipment used to guide treatment delivery, including but not limited to ultrasound units, kV and mV imaging equipment and monitors that are used to view patient imaging studies and personnel radiation safety equipment. Data communication between various systems, including but not limited to treatment planning systems, treatment delivery systems and data networks/storage media must be evaluated and tested to ensure accurate and complete data transfer.
  - (xi) Quality control tests performed on equipment and technology used in planning and implementing radiation treatment must be documented, including:
    - (A) Detailed procedures for performing each test;
    - (B) The frequency of each test;
    - (C) Acceptable results for each test;
    - (D) Corrective actions taken;
    - (E) Record keeping and reporting procedures for test results including the tester's name, signature and date of the test; and
    - (F) The qualifications are specified for the individual conducting the test and for the person who reviews test data.
  - (xii) Test results that exceed tolerances/limits must be immediately reported to the authorized medical physicist or QMP.
  - (xiii) Records for all maintenance, repairs and upgrades of equipment and technology must be maintained for at least 5 years.
  - (xiv) Errors or defects in technology or equipment, including computer hardware and software, must be reported to the technology or equipment manufacturer and to the United States Food and Drug Administration (MedWatch) as soon as possible and in no event more than 30 days of discovery, and records of equipment errors and reports required by this subparagraph must be maintained for review by the Department for at least 3 years.
  - (xv) Patients with permanent brachytherapy implants must be provided with instructions to take radiation safety precautions, as required by 10 CFR §35.75 and the licensee's radioactive materials license, after being released from the licensee's facility.
  - (xvi) All personnel involved in planning or implementing radiation therapy must be credentialed and acting within their scope of practice as provided in New York State law. Credentialing must include verifying that all professional staff are appropriately licensed, including medical physicists and radiation therapy technologists. Records of credentialing must be maintained during the period in which the credentialed person provides services to the licensee or registrant, and for 3 years thereafter.
  - (xvii) Any unintended deviation from the treatment plan that is identified must be evaluated and

- corrective action to prevent recurrence must be implemented. Records of unintended deviations and corrective action must be maintained for audits required by paragraph (5) of this subdivision and for review by the Department.
- (xviii) There must be a process to ensure quick and effective response to any radiation therapy related recalls, notices, safety alerts and hazards.
- (3) Each licensee must adopt and maintain a radiation treatment manual prepared by an authorized medical physicist possessing the qualifications specified in 10 CFR §35.51. The manual must include the calculation methods and formulas to be used at the facility (including the methods for performing the checks of treatment plans and related calculations as required by clause (I) of subparagraph (i) of paragraph (3) of this subdivision). The treatment planning manual may be part of the quality assurance manual. The radiation treatment manual must be included in training given pursuant to 10 CFR §19.12 to facility staff who will participate in treatment planning. Each licensee must ensure that an authorized medical physicist possessing the qualifications specified in 10 CFR §35.51 prepares or reviews and approves a procedures manual describing how radiation therapy treatment planning is to be performed at the licensee's facility and reviews the treatment planning manual at least annually.
- (4) Each licensee must ensure that all equipment used in planning and administering radiation therapy is functioning properly, designed for the intended purpose, properly calibrated, and maintained in accordance with the manufacturer's instructions and the quality assurance program described in the licensee's quality assurance manual. Such equipment must be calibrated prior to use on patients, at least annually thereafter and following any change, repair or replacement of any component which may alter the radiation output.
- (5) Each licensee must implement written procedures for auditing the effectiveness of the radiation therapy quality assurance program that includes the following:
- (i) Audits must be conducted at intervals not to exceed 12 months by an authorized medical physicist possessing the qualifications specified in 10 CFR §35.51, and also by a physician, both of whom are in the active practice of the type of radiation therapy conducted by the licensee; and
  - (ii) The licensee must ensure that the individuals who conduct the audit prepare and deliver to the licensee a report which contains an assessment of the effectiveness of the quality assurance program and makes recommendations for any needed modifications or improvements; and
  - (iii) The licensee must promptly review the audit findings, address the need for modifications or improvements and document actions taken. If recommendations are not acted on, the licensee must document the reasons therefor and also any alternative actions taken to address the audit findings; and
  - (iv) Each licensee must maintain complete written records relating to quality assurance and audit activities for review and inspection by the Department. Audit records must be maintained for at least 6 years.
- (6) Accreditation in Radiation Oncology.
- (i) Each licensee must maintain accreditation in radiation oncology by the American College of Radiology, the American College of Radiation Oncology or other equivalent accrediting organization as determined by the Department.
  - (ii) The licensee must maintain a record of accreditation, including a copy of the application, all supplemental application information and all correspondence transmitted between the accrediting body and the licensee. Records must be maintained for at least 6 years.
- (d) Unsealed byproduct material for which a written directive is required.  
A quality assurance program for unsealed byproduct material for which a written directive is required is a system of plans, actions, reviews, reports and records, the purpose of which is to ensure a consistent and safe fulfillment of the dose prescription.
- (1) Each licensee who uses unsealed byproduct material for which a written directive is required in



humans must implement a quality assurance program which includes at a minimum:

- (i) The adoption of a manual containing written policies and procedures designed to assure effective supervision, safety, proper performance of equipment, effective communication and quality control. The manual must include procedures to assure that:
  - (A) each patient's evaluation and intended treatment is documented in the patient's record;
  - (B) a written, signed and dated order for medical use of radioactive material is made in accordance with 10 CFR §35.40;
  - (C) each patient is positively identified;
  - (D) all orders and other treatment records are clear and legible;
  - (E) staff must be instructed to obtain clarification before treating a patient if any element of the order or other record is confusing, ambiguous or suspected of being erroneous;
  - (F) each patient's response to treatment must be assessed by an authorized user physician, or a physician under the supervision of an authorized user physician, for unsealed byproduct material for which a written directive is required and that unusual responses are evaluated as possible indications of treatment errors; and
  - (G) complete treatment records containing data recorded at the time of each treatment are maintained.
- (2) Each licensee must ensure that all equipment used in planning and administering unsealed byproduct material for which a written directive is required is designed and used for the intended purpose and is properly functioning, is properly calibrated and is maintained in accordance with the manufacturer's instructions and the QA program described in the licensee's QA manual.
- (3) Each licensee must audit its activities related to the use of unsealed byproduct material for which a written directive is required as part of its quality assurance program at intervals not to exceed 12 months to assess the effectiveness of the program, document the audit findings and any modifications or improvements found to be needed and institute corrective actions and improvements as indicated by the audit findings.

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