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Authority

The provisions of this Chapter 221 issued under section 301 of the The Atomic Energy Development and Radiation Control Act (73 P.S. § 1301) (Repealed), unless otherwise noted.

Source

The provisions of this Chapter 221 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 216.3 (relating to exemptions); 25 Pa. Code § 218.1 (relating to purpose and scope); 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees); 25 Pa. Code § 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

GENERAL PROVISIONS**§ 221.1. Purpose and scope.**

This chapter establishes requirements for the use of X-ray equipment by or under the supervision of a licensed practitioner of the healing arts. A registrant or licensee who uses X-rays in the healing arts shall comply with this chapter. This chapter is in addition to, and not in substitution for, other applicable provisions of this article.

Authority

The provisions of this § 221.1 amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (333927).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

AAPM—American Association of Physicists in Medicine.

Air kerma—Kerma in air.

Air kerma rate—Air kerma per unit time.

Aluminum equivalent—The thickness of type 1100 aluminum alloy—the nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, 0.12% copper—affording the same attenuation, under specified conditions, as the material in question.

Automatic exposure control—A device which automatically controls one or more technique factors to obtain at preselected locations a desired quantity of radiation.

Beam axis—A line from the source through the centers of the X-ray fields.

Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

CBCT—Cone beam computed tomography—A digital volume tomography method used in some imaging applications using two-dimensional digital detector arrays and a cone-shaped X-ray beam, instead of fan-shaped, that rotates around to generate a high-resolution 3D image with high geometric accuracy. Reconstruction algorithms can be used to generate images of any desired plane.

CINE—Cineradiography—A motion picture record of successive images appearing on a fluoroscopic screen.

CR—Computed radiography—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. CR systems may use cassettes to house the phosphor or it may be integrated into a DR system.

CT—Computed tomography—The production of a tomogram by the acquisition and computer processing of X-ray transmission data.

Cephalometric device—A device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components—Components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 (42 U.S.C.A. §§ 263b—263n).

Certified system—An X-ray system which has one or more certified components.

Changeable filter—A filter, exclusive of inherent filtration, which can be added to or removed from the useful beam through an electronic, mechanical or physical process.

Coefficient of variation (C)—The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

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

where

s = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample; $n > 1$.

Control panel—The part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

DDR—Direct digital radiography—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.

DR—Digital radiography—

(i) An X-ray imaging method (or radiography) which produces a digital rather than film projection image.

(ii) The term includes CR and DDR.

DRL—Diagnostic reference level—An investigational level, set as a standard by a recognized body (for example, the American College of Radiology, the American Association of Physicists in Medicine, the National Council on Radiation Protection and Measurements or similar), used to identify unusually high radiation doses for common diagnostic medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

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

Dental panoramic system—A device intended to produce a radiographic image of both dental arches on one film.

Diagnostic source assembly—The tube housing assembly with a beam-limiting device attached.

Diagnostic X-ray system—An X-ray system designed for irradiation of a part of the human body for the purpose of diagnosis or visualization.

Direct supervision—A licensed practitioner of the healing arts who exercises general supervision and is present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. The licensed practitioner does not have to be present in the room when the procedure is being performed.

Dose length product—The indicator of the integrated radiation dose from a complete CT examination. It addresses the total scan length by the following formula:

$$\text{DLP (mGy} \cdot \text{cm)} = \text{CTDI}_{\text{vol}} \text{ (mGy)} \times \text{scan length (cm)}$$

Electronic brachytherapy—A modality 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. X-ray devices specifically designed and solely used to treat skin cancer lesions are not considered elec-

tronic brachytherapy devices under this definition and must meet the applicable parts of this title pertaining to registration and use.

Emerging technology—An innovative medical technology that uses an ionizing radiation source.

Entrance exposure rate—The exposure in air per unit time at the point where the center of the useful beam enters the patient.

FGI—Fluoroscopic-guided interventional procedures—An interventional diagnostic or therapeutic high-risk procedure performed by means of percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to do all of the following:

- (i) Localize or characterize a lesion, diagnostic site or treatment site.
- (ii) Monitor the procedure.
- (iii) Control and document the procedure.

Field emission equipment—Equipment using an X-ray tube in which electrons are emitted from the cathode solely by the force between an electric field and the electrons.

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and preferentially absorb selected radiation.

Filtration—The amount of material placed in the useful beam to modify the radiation's characteristics, typically expressed in terms of millimeters of aluminum or copper equivalent.

Fluoroscopic imaging assembly—A subsystem in which X-ray photons produce a fluoroscopic image. The term includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic system—See fluoroscopic imaging assembly.

Focal spot—The area projected on the anode of the X-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General supervision—The overall direction and control of a licensed practitioner of the healing arts. The licensed practitioner is not required to be present during the performance of the procedure.

HVL—Half-value layer—

(i) The thickness of specified material which attenuates the exposure rate by 1/2 when introduced into the path of a given beam of radiation. In 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.

(ii) The term is used to describe the penetrating ability of the radiation.

Healing arts screening—The testing of human beings using X-ray machines for the detection or evaluation of health indications when the tests are not spe-

cifically and individually ordered for the purpose of diagnosis or treatment by a licensed practitioner of the healing arts legally authorized to prescribe the X-ray tests.

Health physics—An application of physics concerned with protection of people and the environment from the biological effects of radiation.

High-risk procedure—Any radiologic procedure that uses energies of less than 1 million electron volts that could exceed skin doses of 200 rad (2.0 Gy).

IORT—Intraoperative radiation therapy—A modality of therapy in which therapeutic levels of ionizing radiation are applied to a target area, such as a cancer tumor, while the area is exposed during surgery.

Image intensifier—An image receptor with electronic amplification, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

Image receptor—A device, such as a fluorescent screen or radiographic film, 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.

Intensifying screen—A fluorescent screen which transforms incident X-ray photons into a visible image.

Intraoral dental radiography—A modality of dental radiography in which the image receptor is placed inside a patient's oral cavity.

kV—Kilovolts

kVp—Peak tube potential (see kilovolts peak).

Kerma—A measure of energy transferred from radiation to matter and means kinetic energy released per unit mass. It is related to, but not the same as, absorbed dose. Unit of measure is gray.

Kilovolts peak (kVp)—The maximum value of the potential difference across the X-ray tube during an exposure.

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

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

- (i) The useful beam.
- (ii) Radiation produced when the exposure switch or timer is not activated.

Leakage technique factors—The technique factors associated with the tube housing assembly which are used in measuring leakage radiation defined as follows:

- (i) 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 charge per exposure being 10 millicoulombs—10 milliamperere seconds—or the minimum charge obtainable from the unit, whichever is larger.

(ii) 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.

(iii) For other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Licensed practitioner of the healing arts—An individual licensed by the Commonwealth to practice the healing arts, which for the purposes of this article shall be limited to medicine, surgery, dentistry, osteopathy, podiatry and chiropractic.

Light field—The area defined by the intersection of the light beam with a plane parallel with the plane of the image receptor. The edge of the field is defined by the points at which the light intensity is 25% of the maximum light intensity in the plane.

Line-voltage regulation—The difference between the no-load and the load line potentials expressed as a percent of the load line potential calculated using the following equation:

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

where

V_n = No-load line potential and

V_l = Load line potential.

Low-risk procedure—Any radiologic procedure that is not a high-risk procedure.

mA—Milliampere.

mAs—Milliampere second.

mR—Milliroentgen.

Maximum line current—The root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

Medical physics—An application of physics that addresses the needs of medicine or health care. Subfields of medical physics include the following:

- (i) Therapeutic medical physics.
- (ii) Diagnostic medical physics or imaging.
- (iii) Nuclear medical diagnostic or molecular imaging and therapy.
- (iv) Medical health physics or radiation protection.

Mobile X-ray system—See X-ray equipment.

Patient—An individual subjected to healing arts examination, diagnosis or treatment.

Peak tube potential—The maximum value of the potential difference across the X-ray tube during an exposure.

Performance phantom—A device specifically approved by the QMP or QE for evaluation of operational conformance with tolerances established by the QMP, QE or manufacturer.

Personal supervision—A licensed practitioner of the healing arts who exercises general supervision and is present in the room or adjacent control area during the performance of the procedure.

Phototimer—A method for controlling the radiation exposures to an image receptor by measuring the radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated.

Portable radiation system—See X-ray equipment.

Portable X-ray system—See X-ray equipment.

Position indicating device (PID)—A device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance.

Positive beam limitation—The automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby an X-ray exposure cannot be made without an adjustment.

Protective apron—An apron incorporating radiation absorbing materials.

Protective barrier—A barrier of radiation absorbing material used to reduce radiation exposure. The term includes the following types:

(i) *Primary protective barrier*—Material used to reduce radiation exposure from the useful beam.

(ii) *Secondary protective barrier*—Material used to reduce exposure from stray, leakage or scattered radiation.

QE—Qualified expert—The term as defined in § 215.2 (relating to definitions).

QMP—Qualified medical physicist—An individual who is competent to independently provide clinical professional services and practices only in health or radiological physics, or in the subfields of medical physics.

(i) A QMP meets all of the following credentials:

(A) Certified in the field of medical physics, radiological physics, medical health physics or health physics by an appropriate national certifying body recognized by the Department.

(B) Complies with the certifying body's requirements for continuing education and recertification.

(C) Provides clinical professional services and practices only in health/radiological physics or in one or more of the subfields of medical physics, consistent with the individual's training and experience, and in accordance with the individual's respective certifying body's code of ethics.

(ii) An individual who does not meet the requirements of subparagraph (i) shall meet each of the following credentials to qualify as a QMP:

(A) Has earned a master's or doctoral degree, or both, in physics, medical physics, biophysics, radiological physics, health physics or equivalent disciplines from an accredited college or university.

(B) Has 3 years of documented relevant clinical training and experience in each of the subfields in the definition of “medical physics,” under the supervision of a QMP who is qualified to practice in the same subfield, for each of the areas in which the individual intends to practice.

(C) Completes the continuing education requirements of an applicable certifying body of health/radiological physics or in one or more of the subfields of medical physics in which the individual practices.

(iii) An individual who has been practicing as a QMP in health/radiological physics or in one or more of subfields of medical physics for at least 5 years prior to January 24, 2019, is exempt from the requirements of subparagraphs (i) and (ii). Documentation of at least 5 years of practicing as a QMP in health/radiological physics or in one or more of the subfields of medical physics must be maintained for each of the fields or subfields, or both, in which the individual practices. As of January 24, 2019, an individual who qualifies as a QMP under this subparagraph shall meet the continuing education requirements in subparagraph (ii)(C).

Radiation therapy simulation system—A radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph—An image receptor on which an image is created directly or indirectly by an X-ray pattern and results in a permanent record.

Radiographic imaging system—A system whereby an image is produced on an image receptor by the action of ionizing radiation.

Radiological physics—See health physics.

Rating—The operating limits specified by the component manufacturer.

Registrant—A person who is legally obligated to register with the Department under this article and the act.

Research—One of the following:

(i) Theoretical analysis, exploration or experimentation.

(ii) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental testing of models, devices, equipment, materials and processes. The term includes the external administration of X-ray radiation to human beings for diagnostic or therapeutic purposes or in an equivalent manner as a diagnostic or therapeutic procedure.

SID—Source-image receptor distance—The distance from the source to the center of the input surface of the image receptor.

SRDL—Substantial radiation dose level—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.

SSD—The distance between the source and the skin of the patient.

Scattered radiation—Radiation that, during passage through matter, has been deviated in direction.

Screening—See the definition of “healing arts screening.”

Serial radiography—Radiographic images produced in regular sequence.

Shutter—A device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

Source—The focal spot of the X-ray tube.

Specific prescription—A written or oral directive authorizing a radiographic or fluoroscopic examination of a specified individual.

Spot check—A procedure to assure that a previous calibration continues to be valid.

Spot film—A radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device—A device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. The term includes a device intended to hold a cassette in front of the input end of an image intensifier for the purpose of making a radiograph.

Stray radiation—The sum of leakage and scattered radiation.

Technique factors—The following conditions of operation:

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

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV, number of X-ray pulses and either tube current or product of tube current and time.

(iii) For 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.

Therapeutic X-ray system—A system design for irradiation of a part of the human body for the purpose of treatment or alleviation of symptoms of disease.

Timer—An electronic device which is capable of measuring an X-ray exposure.

Tube—An X-ray tube, unless otherwise specified.

Tube housing assembly—The tube housing with the X-ray tube installed. The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

Unintended dose—A radiation dose in diagnostic or interventional X-ray resulting from an error in procedure or equipment malfunction.

Useful beam—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.

Visible area—The portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

Wedge filter—An added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray control—A device which controls input power to the X-ray high-voltage generator or the X-ray tube, or both. The term includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.

X-ray equipment—An X-ray system, subsystem or component thereof. Types of X-ray equipment are as follows:

- (i) *Mobile X-ray equipment*—X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
- (ii) *Portable X-ray equipment*—X-ray equipment designed to be hand-carried.
- (iii) *Stationary X-ray equipment*—X-ray equipment which is installed in a fixed location or vehicle.

X-ray field—The area defined by the intersection of the useful beam with a plane parallel with the plane of the image receptor. The edge of the field is defined by the points at which the exposure rate is 25% of the maximum exposure rate in the plane.

X-ray high-voltage generator—A device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential.

X-ray subsystem—A combination of two or more components of an X-ray system.

X-ray system—An assembly of components for the controlled production of X-rays. The term 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 tube—An electron tube which is designed to be used primarily for the production of X-rays.

Authority

The provisions of this § 221.2 amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20); and the Radon Certification Act (63 P.S. §§ 2001—2014).

Source

The provisions of this § 221.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended May 16, 2008, effective May 17, 2008, 38 Pa.B. 2243; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (333927) to (333934).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 219.229 (relating to diagnostic or interventional procedure medical reports); 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.201 (relating to definitions).

§ 221.3. [Reserved].**Source**

The provisions of this § 221.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved May 16, 2008, effective May 17, 2008, 38 Pa.B. 2243. Immediately preceding text appears at serial page (304486).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

ADMINISTRATIVE CONTROLS**§ 221.11. Registrant responsibilities.**

(a) The registrant is responsible for directing the operation of X-ray systems under his administrative control and shall assure that the requirements of this article are met in the operation of the X-ray systems.

(b) An individual who operates an X-ray system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include items included in Appendix A (relating to determination of competence) and there shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

(1) The operator or the individual who supervises the operation of a high-risk procedure shall have additional instruction, which may include certification or registration in the applicable specialty by a professional organization recognized by the Department. Continuing education for high-risk procedures shall occur, at a minimum, every 2 years.

(2) Continuing education for all other (low-risk) procedures shall occur, at a minimum, every 4 years.

(c) Protocol information, which specifies the techniques for examinations performed with the system, shall be provided in the vicinity of each diagnostic X-ray system's control panel. The protocol shall include information pertinent to the particular examination, such as:

(1) The patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized.

(2) The type and size of the image receptor or film-screen combination.

(3) The type of grid, if any.

(4) The type and location of placement of patient shielding, for example, gonad, and the like.

(5) For mammography, indication of kVp/target/filter combination.

- (6) Source to image receptor distance to be used, except for dental intraoral radiography.
- (d) Written safety procedures and rules shall be available at a facility including restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with the rules.
- (e) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. The following apply for individuals other than the patient being examined:
- (1) Individuals shall be positioned so that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent material. The lead equivalent of the material is to be determined at 60 kV.
 - (2) All persons required for the medical procedure shall be protected from the stray radiation by protective aprons or whole protective barriers of at least 0.25 millimeter lead equivalent or shall be so positioned that the persons are not in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.
 - (3) A patient who cannot be removed from the room shall be protected from the stray radiation by protective barriers of at least 0.25 millimeter lead equivalent material unless the shield would compromise the health of the individual or shall be so positioned that the patient is not in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.
 - (4) No individual, other than the patient being examined, may be in the useful beam, unless required to conduct the procedure.
- (f) During diagnostic procedures in which the gonads are in the useful beam, gonad shielding of at least 0.5 millimeter lead equivalent shall be used for patients except for cases in which this would interfere with the diagnostic procedure.
- (g) An individual may not be exposed to the useful beam except for healing arts purposes or under § 221.15 (relating to use of X-rays in research on humans). An exposure shall be authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
- (1) Exposure of an individual for training, demonstration or other nonhealing arts purposes.
 - (2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Department. When requesting authorization, the registrant shall submit the information outlined in § 221.13 (relating to information to be submitted by persons requesting approval to conduct healing arts screening).

(h) If a patient or image receptor requires auxiliary support during a radiation exposure the following apply:

- (1) Mechanical holding devices shall be used when the technique permits.
- (2) The human holder shall be protected as required by subsection (e).
- (3) An individual may not be used routinely to hold image receptors or patients.

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

(j) The screen and film system used shall be spectrally compatible. Defective screens may not be used for diagnostic radiological imaging.

(k) With the exception of intraoral dental radiography, film may not be used without intensifying screens for routine diagnostic radiological imaging.

(l) The registrant shall have a quality assurance program. This quality assurance program shall be documented and be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. At a minimum, the quality assurance program shall address repeat rate, DRLs, image recording, processing and viewing, image quality and artifacts, and maintenance and modifications to the quality assurance program. For CT, each study shall be checked. If an artifact is present, the registrant shall take corrective action as appropriate. Records shall be maintained by the registrant for inspection by the Department for 5 years. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request.

(m) Neither the X-ray tube housing nor the collimating device may be handheld during the exposure unless specifically designed to be handheld.

(n) Functional damage to a patient organ or a physiological system that results from a prescribed causative procedure shall be reported to the Department as outlined in § 219.229 (relating to diagnostic or interventional procedure medical reports).

(o) The registrant shall maintain records documenting the QMP's qualifications and compliance with continuing education requirements.

Authority

The provisions of this § 221.11 amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (333934), (304487) to (304488) and (333935).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.42a (relating to control of scattered radiation).

§ 221.12. Records, maintenance and associated information.

The registrant shall maintain records of surveys, calibrations, maintenance and modifications performed on the X-ray systems including the names of persons who performed the services. The registrant shall keep these records for inspection by the Department for 5 years.

Authority

The provisions of this § 221.12 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123681).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.13. Information to be submitted by persons requesting approval to conduct healing arts screening.

(a) The Department will consider efficacy as a factor in evaluating healing arts screening procedures. In its review, the Department will consider National medical organization consensus statements as well as peer reviewed scientific and medical literature that addresses the efficacy of the proposed screening procedures. The review may also consider relevant information from appropriate Federal agencies. For procedures that result in an individual organ dose or deep dose equivalent greater than 1 mSv (100 mrem) to a screened individual the Department will consult with the Department of Health (DOH) for assistance in reviewing the efficacy of the proposed procedures but the final decision will remain that of the Department. The DOH will have access to all relevant materials when rendering its review.

(b) A person requesting that the Department approve a healing arts screening program other than mammography shall submit in writing the following information for evaluation by the Department. If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

- (1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.
- (2) The diseases or conditions for which the X-ray examinations are to be used.

- (3) The description in detail of the X-ray examinations proposed in the screening program.
 - (4) A description of the population to be examined in the screening program—age, sex, physical condition and other appropriate information.
 - (5) An evaluation of all known alternate methods that could achieve the goals of the screening program and why these methods are not used in preference to the proposed X-ray examinations.
 - (6) An evaluation by a qualified expert of the X-ray systems to be used in the screening program. The evaluation must show that the systems satisfy the requirements of this article. The evaluation must include a measurement of patient entrance exposures and calculation of the maximum shallow dose, deep dose equivalent and organ dose from the X-ray examinations to be performed.
 - (7) A description of the diagnostic X-ray quality control program.
 - (8) A copy of the technique chart for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.
 - (9) The qualifications of all individuals who will be operating the X-ray systems.
 - (10) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.
 - (11) The name, address and qualifications of the individual who will interpret the screening procedure results.
 - (12) A description of the information and procedure for advising the individuals screened of the potential for false positive or negative results and the implications for the patient; the procedure for recording informed consent for the procedure following disclosure of this information; and the procedure for advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and further medical needs indicated.
 - (13) A description of the procedures for the retention or disposition of the diagnostic images, data and other records pertaining to the X-ray examination.
 - (14) An approximation of the frequency of screening activities and duration of the entire screening program.
- (c) Mammography facilities shall comply with 21 CFR Part 900 (relating to mammography).

Authority

The provisions of this § 221.13 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); and the Radon Certification Act (63 P. S. §§ 2001—2014).

Source

The provisions of this § 221.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended May 16, 2008, effective May 17, 2008, 38 Pa.B. 2243. Immediately preceding text appears at serial pages (304489) to (304491).

Cross References

This section cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities); and 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.14. [Reserved].**Source**

The provisions of this § 221.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

§ 221.15. Use of X-rays in research on humans.

(a) Registrants conducting research using X-rays involving human subjects are exempted from the requirements of this section if the research is conducted, funded, regulated or supported by a Federal agency which has implemented the Federal policy for the protection of human subjects or if the research is carried out in an institution which conducts other Federally funded or supported human research and follows all Federal requirements for protocol review and research subject protection.

(b) If not exempted under subsection (a), a person shall submit, in writing, the following information and evaluation to the Department and receive approval by the Department before conducting the research. If the information submitted to the Department becomes invalid or outdated, the person shall immediately, in writing, notify the Department.

(1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.

(2) A description of the population to be examined in the research program, age, sex, physical condition and other appropriate information.

(3) An evaluation of all known alternate methods that could achieve the goals of the research program and why these methods are not used in preference to the X-ray examinations.

(4) An evaluation by a qualified expert of the X-ray system to be used in the research program. This evaluation shall show that the system satisfies the requirements of this article. The evaluation shall include a projected measurement of individual and cumulative patient exposures from the X-ray examinations to be performed.

(5) A description of the diagnostic X-ray quality control program.

(6) A copy of the technique chart which specifies the information for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.

(7) The qualifications of all individuals who will be operating the X-ray system.

(8) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

(9) The name, address and qualifications of the individual who will interpret the data.

(10) A copy of the research protocol authorized by a committee consisting of at least three qualified persons. At least one of the committee members shall be knowledgeable in radiation effects on humans.

(11) The provisions for independent institutional review.

(c) Proposed subjects or their legal representative shall sign a statement acknowledging that they have been informed of their anticipated radiation exposure and possible consequences arising from this exposure.

Authority

The provisions of this § 221.15 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.15 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3238. Immediately preceding text appears at serial pages (249287) to (249288).

Cross References

This section cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities); and 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.16. Training, competency and continuing education.

(a) *Training and competency.* The registrant shall ensure that:

(1) An individual who operates X-ray equipment during diagnostic or interventional procedures or supervises the operation of X-ray equipment during a procedure is trained and competent in all of the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

- (i) Basic properties of radiation.
- (ii) Units of measurement.
- (iii) Sources of radiation exposure.
- (iv) Methods of radiation protection for patients and others.
- (v) Biological effects of radiation exposure.
- (vi) Facility-specific and modality-specific X-ray equipment.

- (vii) Facility-specific and modality-specific image recording and processing.
 - (viii) Patient exposure and positioning.
 - (ix) Facility-specific and modality-specific procedures.
 - (x) Facility-specific and modality-specific quality assurance.
 - (xi) Facility-specific and modality-specific dose reduction, monitoring and recording procedures.
 - (xii) Units of measurement and dose, such as dose-area product values, CT dose index and air kerma.
 - (xiii) Factors affecting fluoroscopic outputs.
 - (xiv) High-level control options.
 - (xv) Dose management including dose reduction techniques, monitoring and recording.
 - (xvi) Principles and operation of the specific fluoroscopic X-ray system to be used.
 - (xvii) Fluoroscopic and fluorographic outputs of each mode of operation on the system to be used clinically.
 - (xviii) Applicable State and Federal regulations.
- (2) An individual who operates X-ray equipment during potentially high-risk diagnostic or interventional procedures or supervises the operation of X-ray equipment during these procedures is registered or credentialed and privileged in the applicable specialty by a professional organization recognized by the Department.
- (3) Documentation demonstrating compliance with this section is maintained for inspection by the Department.
- (b) *Continuing education.*
- (1) The registrant shall ensure that individuals who operate X-ray equipment during diagnostic or interventional procedures or supervise the operation of X-ray equipment during a procedure complete continuing education in biological effects of radiation, quality assurance and quality control, and radiation safety, including concepts for minimizing patient and occupational dose and emerging technologies.
- (i) An individual who performs low-risk procedures shall complete continuing education every 4 years.
 - (ii) An individual who performs high-risk procedures shall complete continuing education every 2 years. In addition to the topics in this paragraph, the continuing education must include facility and X-ray unit-specific methods to manage patient dose.
- (2) Documentation of continuing education must be maintained for inspection by the Department for 5 years.

Authority

The provisions of this § 221.16 issued under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of the Administrative Code (71 P.S. § 510.20).

Source

The provisions of this § 221.16 adopted October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); 25 Pa. Code § 221.64 (relating to CBCT); and 25 Pa. Code § 221.205 (relating to operating procedures).

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS**§ 221.21. Diagnostic equipment requirements.**

(a) Diagnostic systems incorporating one or more certified components shall comply with 21 CFR 1020.30—1020.33.

(b) Equipment registered after January 24, 2019, must comply with 21 CFR 1010.2 (relating to certification).

Authority

The provisions of this § 221.21 amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (304493).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.22. Battery charge indicator.

On battery-powered X-ray generators, the control panel shall have means to indicate visually whether the battery is adequately charged for proper operation.

Authority

The provisions of this § 221.22 amended under section 302 of the Radiation Protection Act (35 P.S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

221-20.1

§ 221.23. 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 may not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Authority

The provisions of this § 221.23 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.24. Radiation from components other than the diagnostic source assembly.

The radiation emitted by a component other than the diagnostic source assembly may not exceed 2 milliroentgens (.516 $\mu\text{C}/\text{kg}$) in 1 hour at 5 centimeters from an accessible surface of the component when it is operated in an assembled X-ray system under conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Authority

The provisions of this § 221.24 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4882) to (4883).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.25. Beam quality.

(a) Diagnostic X-ray systems shall have filtration that satisfies the requirements of Table I. The requirements of this section shall be considered to have been met if it can be demonstrated that the half value layer of the primary beam is not less than that shown in Table II.

221-20.2

TABLE I*Filtration Required vs. Operating Voltage*

<i>Operating Voltage (kVp)</i>	<i>Total Filtration (inherent plus added) (millimeters aluminum equivalent)</i>
Below 50	0.5 millimeters
50—70	1.5 millimeters
Above 70	2.5 millimeters

TABLE II**X-Ray Tube Voltage (kilovolt peak)**

<i>Design Operating Range</i>	<i>Measured Operating Potential</i>	<i>Minimum HVL (mm of Aluminum)</i>		
		<i>Specified Dental Systems¹</i>	<i>Other X-Ray Systems²</i>	<i>Other X-Ray Systems³</i>
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
140	3.8	3.8	5.0	
	150	4.1	4.1	5.4

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

² Dental X-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other X-ray systems subject to this section and manufactured before June 10, 2006.

³ All X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

Note: Half-value layers for kilovoltages not listed in Table II may be determined by interpolation or extrapolation.

(b) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(c) For capacitor energy storage equipment, compliance with this section shall be determined with the maximum quantity of charge per exposure.

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

(e) For X-ray systems having variable filtration in the useful beam, a means shall be provided to prohibit exposure unless the filtration requirements of subsection (a) are met for the kVp selected.

Authority

The provisions of this § 221.25 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.25 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3238; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (304494) to (304496).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.26. Multiple tubes.

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

Authority

The provisions of this § 221.26 issued under section 302 of the Radiation Protection Act (35 P.S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.26 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.27. Mechanical support of tube head.

The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

Authority

The provisions of this § 221.27 issued under section 302 of the Radiation Protection Act (35 P.S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

221-20.4

Source

The provisions of this § 221.27 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.28. Technique indicators.

(a) The technique factors for radiographic systems shall be indicated before exposure except for units utilizing automatic exposure controls, in which case the maximum mAs shall be indicated.

(b) The requirement of subsection (a) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by a fluoroscopist.

Authority

The provisions of this § 221.28 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.27 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123686).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.29. Kilovoltage (kV) accuracy.

(a) For variable kV units, the kV output may not vary from the set-indicated value by more than 10% over the range of technique factors normally used. Discrepancies of more than 10% between set-indicated and measured kV values shall be investigated by a qualified expert or service agent and appropriate action taken.

(b) For fixed kV units, the kV output may not vary from the set-indicated value by more than 20% over the range of technique factors normally used. Discrepancies of more than 20% between set-indicated and measured kV values shall be investigated by a qualified expert or service agent and appropriate action taken.

Authority

The provisions of this § 221.29 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.29 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285672) to (285673).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.30. Exposure reproducibility for noncertified systems.

The coefficient of variation of exposure reproducibility may not exceed 0.10 when technique factors are held constant. This requirement shall be deemed to have been met when four exposures are made. This requirement applies when either manual techniques or automatic exposure control is used.

Authority

The provisions of this § 221.30 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); and the Radon Certification Act (63 P. S. §§ 2001—2014).

Source

The provisions of this § 221.30 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended May 16, 2008, effective May 17, 2008, 38 Pa.B. 2243. Immediately preceding text appears on serial page (304498).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.31. [Reserved].**Source**

The provisions of this § 221.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123686) to (123688).

§ 221.31a. Locks.

Position locking, holding and centering devices on X-ray systems shall function as intended.

Authority

The provisions of this § 221.31a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.31a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.32. [Reserved].**Source**

The provisions of this § 221.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123688).

§ 221.32a. Radiographic beam limitation.

- (a) The useful beam shall be limited to the area of clinical interest.
- (b) The beam limiting device shall do one of the following:
 - (1) Indicate numerically the field size in the plane of the image receptor to which it is adjusted to within 2% of the SID.
 - (2) Provide for visually defining the perimeter of the X-ray field except for systems designed for one image receptor size. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field may not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.
- (c) A means shall be provided for stepless (continuous) adjustment of the size of the X-ray field except for systems which use removable fixed operation beam limiting devices.
- (d) A means shall be provided to:
 - (1) Indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor if the angle between the axis of the X-ray beam and the plane of the image receptor is variable. This paragraph does not apply to portable, mobile or intraoral dental units.
 - (2) Align the center of the X-ray field with respect to the center of the image receptor to within 2% of the SID.
 - (3) Indicate the SID to within 2%.
- (e) Intraoral dental X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD to not less than either of the following:
 - (1) Eighteen centimeters if operable above 50 kVp.
 - (2) Ten centimeters if not operable above 50 kVp.
- (f) Indication of field size dimensions and SIDs shall be specified so that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(g) Intraoral dental systems designed for use with an intraoral image receptor shall be provided with a means to limit the X-ray beam so that:

(1) Eighteen centimeters or more, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

(2) Less than 18 centimeters, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(h) When positive beam limitation is used, the following conditions shall be met:

(1) The radiation beam may not be larger than the linear dimensions of the image receptor being used.

(2) The positive beam limitation device shall allow the operator to further reduce the size of the radiation field.

(i) Mobile or portable X-ray systems, other than intraoral dental X-ray systems, shall be provided with a means to limit the source-to-skin distance to at least 30 centimeters.

(j) Radiographic equipment designed for one or more image receptor sizes at a fixed SID shall be provided with a means to accomplish one of the following:

(1) Limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and align the center of the X-ray field with the center of the image receptor to within 2% of the SID.

(2) The X-ray field shall be sized and aligned so that at the plane of the image receptor, it does not extend beyond the edge of the image receptor by more than 2% of the SID.

Authority

The provisions of this § 221.32a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20) and the Radon Certification Act (63 P. S. §§ 2001—2014).

Source

The provisions of this § 221.32a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended May 16, 2008, effective May 17, 2008, 38 Pa.B. 2243. Immediately preceding text appears at serial pages (304499) and (304500).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.33. [Reserved].

Source

The provisions of this § 221.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123688) to (123689).

§ 221.33a. Radiation from capacitor energy storage equipment in standby status.

Radiation emitted from an X-ray tube when the exposure switch or timer is not activated may not exceed a rate of 2 milliroentgens (0.516 $\mu\text{C}/\text{kg}$) per hour at 5 centimeters from an accessible surface of a fully charged diagnostic source assembly, with the beam-limiting device fully open.

Authority

The provisions of this § 221.33a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.33a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (249295) to (249296).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.34. [Reserved].

Source

The provisions of this § 221.34 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123690).

§ 221.34a. Radiation exposure control.

(a) *Radiation exposure control.* A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure may not be initiated without such an action.

(b) *Visual indication and audible signal.* A means shall be provided for visual indication observable from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

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

(d) *Manual exposure control.* An X-ray control shall be incorporated into each X-ray system which allows the operator to terminate an exposure at any time except for one or more of the following:

- (1) Exposure of 1/2 second or less.

(2) During serial radiography in which case a means shall be provided to permit completion of any single exposure of the series in process.

(e) *Automatic exposure control.*

(1) Indication shall be made on the control panel when this mode of operation is selected.

(i) A means shall be provided to terminate irradiation at an appropriate exposure for the projection if the automatic exposure control fails to terminate irradiation.

(ii) A visible signal shall indicate when an exposure has been terminated at the limits required by subparagraph (i), and manual resetting shall be required before further automatically timed exposures can be made.

(2) For X-ray systems operating in automatic exposure control mode, and which lack engineered safeguards that prevent exposure in the event of either a malfunction or a mispositioned X-ray beam with respect to film cassette sensors, the back-up or default mAs shall be set by the operator to an appropriate maximum value for the projection.

(3) X-ray systems utilizing automatic exposure control, in which the back-up mAs values are preset and cannot be selected by the operator, shall prominently indicate the preset mAs value on the console, along with an appropriate warning notice to the operator.

(f) *Exposure control location.*

(1) Stationary X-ray systems shall have X-ray controls permanently mounted in a protected area and situated so that the operator is required to remain in that protected area during the entire exposure.

(2) For mobile and portable X-ray systems the exposure switch shall be arranged so that the operator can stand at least 2 meters from the patient and from the tube head and away from the direction of the useful X-ray beam.

Authority

The provisions of this § 221.34a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.34a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.35. [Reserved].

Source

The provisions of this § 221.35 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123690) to (123691).

§ 221.35a. Fluoroscopic X-ray systems.

(a) *General requirements.* Fluoroscopic X-ray systems shall use an image intensifier and, in addition to the requirements of §§ 221.1—221.34a, shall meet the requirements of §§ 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate).

(b) *Operator qualifications.* In addition to the applicable sections of these regulations, the operation of a fluoroscopic X-ray system for clinical purposes is limited to:

(1) A licensed practitioner working within his scope of practice.

(2) A Department-recognized radiologist assistant working within his scope of practice and under the direct supervision of a licensed practitioner working within his scope of practice.

(3) An individual who passed the American Registry of Radiologic Technologists exam or equivalent, holds a valid certification and is under the personal supervision of a licensed practitioner working within his scope of practice.

(4) A medical resident, radiologist assistant or radiologic technology student in training who is under the personal supervision of a licensed practitioner working within his scope of practice.

(c) *QMP evaluations.* Fluoroscopic equipment shall be evaluated by or under the direction of a QMP within 30 days after installation and after any maintenance of the system that may affect the exposure rate. Thereafter, evaluations shall be made at intervals not to exceed 14 months from the date of the prior evaluation by or under the direction of a QMP. At a minimum, evaluations shall include all of the following:

(1) A measurement of entrance exposure rates over a representative range of attenuating materials in all modes clinically used, including fluoroscopy, high-level control, acquisition and CINE, when available. Measurements shall be performed with a dosimetry system calibrated within 2 years preceding the measurements. Records of these output measurements shall be maintained for 5 years for inspection by the Department. Measurements shall be made as follows:

(i) For systems without automatic exposure control, by utilizing an mA and kVp typical of the clinical use of the fluoroscopic system.

(ii) For systems with automatic exposure control, by utilizing sufficient attenuating material in the useful beam to produce an mA and kVp typical of the clinical use of the fluoroscopic system.

(2) A measurement and verification of compliance with maximum air kerma rate for fluoroscopy and high-level control, if available.

(3) An evaluation of high-contrast resolution and low-contrast resolution in both fluoroscopic and spot-film or digital acquisition modes.

(4) An evaluation of the operation of the 5-minute timer, warning lights, interlocks and collision sensors.

- (5) An evaluation of the beam quality.
 - (6) An evaluation of the collimation in the fluoroscopy and spot-film or digital acquisition modes.
 - (7) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.
 - (8) An evaluation of any changes that may impact patient and personnel exposure.
- (d) *Additional requirements for facilities performing FGI.*
- (1) The registrant utilizing FGI studies shall establish and implement written procedures, or procedures documented in an electronic reporting system, that include all of the following:
 - (i) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes.
 - (ii) A method to be used to monitor patient radiation dose during FGI.
 - (iii) Dose notification levels, as appropriate, at which the physician is notified for actions that may be taken for patient safety.
 - (iv) SRDL values referencing or consistent with nationally-recognized standards.
 - (v) Actions to be taken for cases when an SRDL is exceeded, which may include patient follow-up.
 - (vi) A review of the established procedures at an interval not to exceed 12 months.
 - (2) Records of policies and procedures shall be maintained for inspection by the Department. If the registrant revises a policy or procedure, documentation shall be maintained that includes the justification for the revision.
 - (3) A record of radiation output information shall be maintained so the radiation dose to the skin may be estimated in accordance with established protocols. The record must include all of the following:
 - (i) Patient identification.
 - (ii) Type and date of examination.
 - (iii) Identification of the fluoroscopic system used.
 - (iv) Peak skin dose, cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.
 - (4) If the peak skin dose, cumulative air kerma or dose area product is 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 one or more of the following:
 - (i) Fluoroscopic mode, such as high-level or pulsed mode of operation.
 - (ii) Cumulative fluoroscopic exposure time.
 - (iii) Number of films or recorded exposures.
 - (5) The registrant shall maintain records for 5 years for inspection by the Department.

Authority

The provisions of this § 221.35a issued and amended under sections 301 and 302 of the Radiation Protection Act (31 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.35a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (304503).

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.36. [Reserved].**Source**

The provisions of this § 221.36 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123691).

§ 221.36a. Limitation of useful beam of fluoroscopic equipment.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-to-image receptor distance.

(b) The X-ray tube used for fluoroscopy may not produce X-rays unless a barrier is in position to intercept the useful beam and the imaging device is in place and operable.

(c) A means shall be provided for stepless (continuous) adjustment of the field size.

(d) The minimum field size at the greatest source to image receptor distance shall be containable in a square of 5 centimeters by 5 centimeters unless otherwise provided in 21 CFR 1020.32(b) (relating to fluoroscopic equipment).

(e) Equipment may not be operated at a source to skin distance less than 30 centimeters or as required under 21 CFR 1020.32(g).

(f) The width of the X-ray field in the plane of the image receptor may not exceed that of the visible area of the image receptor by more than 3% of the source to image receptor distance. The sum of the excess length and the excess width may not be greater than 4% of the source to image receptor distance.

(g) For rectangular X-ray fields used with a circular image receptor, the error in alignment shall be determined along the length and width dimensions of the X-ray field which passes through the center of the visible area of the image receptor.

(h) Compliance with subsections (a)—(g) shall be determined with the beam axis perpendicular to the plane of the image receptor.

(i) Spot-film devices shall meet the following additional requirements:

(1) A means shall be provided between the source and the patient for adjustment of the X-ray field size to the size of the portion of film which has been selected on the spot-film selector.

(2) The adjustments shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the film.

(3) The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor may not exceed 3% of the source-to image receptor when adjusted for full coverage of the selected portion of the image receptor.

(4) The sum, without regard to sign, of the misalignment along any two orthogonal dimensions, may not exceed 4% of the source to image receptor distance.

(5) The center of the X-ray field in the plane of the film shall be aligned with the center of the film within 2% of the source to image receptor distance.

Authority

The provisions of this § 221.36a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.36a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285678) to (285679).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.37. [Reserved].

Source

The provisions of this § 221.37 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123691) to (123692).

§ 221.37a. Activation of fluoroscopic tube.

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

Authority

The provisions of this § 221.37a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.37a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.38. [Reserved].**Source**

The provisions of this § 221.38 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123692).

§ 221.38a. Entrance exposure rate.

(a) *Fluoroscopic systems without high level control.* The exposure rate may not exceed 10 roentgens (2.58 mC/kg) per minute except during recording of fluoroscopic images.

(b) *Fluoroscopic systems with high level control.*

(1) When the high level control is activated, the maximum exposure rate shall be 20 roentgens (5.16 mC/kg) per minute.

(2) When the high level control is not activated, the maximum exposure rate shall be 10 roentgens (2.58 mC/kg) per minute.

(3) Special means of activation of high level controls are required. The high level control shall only be operable when continuous manual activation is provided by the operator.

(4) There shall be an indication to the fluoroscopist that the high level control is being used.

(c) *Frequency of output measurements.* Output measurements to show compliance with this section shall be made at least annually and after maintenance that could affect the output of the machine.

(d) *Compliance requirements.* Compliance with subsections (a)—(c) shall be determined as follows:

(1) If the source is below the table, the exposure rate shall be expressed for the center of the useful beam 1 centimeter above the tabletop or cradle with the image intensifier 30 centimeters above the tabletop or cradle.

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

(3) In a c-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source at its closest possible position of operation.

(4) The tube potential and current shall be set to give the maximum exposure possible from the X-ray system. For systems with automatic exposure control, at least 3 millimeters of lead shall be placed between the measuring device and image receptor.

(5) The measurement shall be made at the center of the useful beam.

Authority

The provisions of this § 221.38a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.38a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.39. [Reserved].

Source

The provisions of this § 221.39 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123692) to (123693).

§ 221.39a. Barrier transmitted radiation rate limits.

The protective barrier may not transmit more than 2 milliroentgens (.516 $\mu\text{mC}/\text{kg}$) per hour at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly for each roentgen per minute of entrance exposure rate.

Authority

The provisions of this § 221.39a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.39a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.40. [Reserved].

Source

The provisions of this § 221.40 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123693).

§ 221.40a. Indication of tube voltage and current.

During fluoroscopy and cinefluorography, the voltage and the current shall be continuously indicated.

Authority

The provisions of this § 221.40a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.40a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.41. [Reserved].**Source**

The provisions of this § 221.41 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123693).

§ 221.41a. Fluoroscopic timer.

A cumulative timing device activated by the fluoroscope switch shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary or permanent interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

Authority

The provisions of this § 221.41a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.41a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.42. [Reserved].**Source**

The provisions of this § 221.42 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123694).

§ 221.42a. Control of scattered radiation.

(a) Fluoroscopic table designs when combined with normal operating procedures shall be of a type so no unprotected part of the staff or an ancillary indi-

vidual's whole body is exposed to unattenuated scattered radiation which originates from under the table. The attenuation required may be not less than .25 millimeter lead equivalent.

(b) Equipment configuration when combined with normal operating procedures shall be of a type so that no portion of the staff or an ancillary individual's whole body, except the extremities, is exposed to the unattenuated scattered radiation emanating from above the table top unless one of the following criteria is met:

- (1) The individual is at least 120 centimeters from the center of the useful beam.
- (2) The radiation has passed through at least .25 millimeter of lead equivalent material—for example, drapes, bucky-slot cover (film-tray cover panel), sliding or folding panel or self supporting curtains—in addition to lead equivalency provided by the protective apron referred to in § 221.11(e) (relating to registrant responsibilities).

Authority

The provisions of this § 221.42a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.42a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.43. [Reserved].

Source

The provisions of this § 221.43 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123694) to (123695).

§ 221.43a. Mobile fluoroscopes.

In addition to the other requirements of §§ 221.35a—221.42a, mobile fluoroscopes shall provide image intensification.

Authority

The provisions of this § 221.43a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.43a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§§ 221.44—221.49. [Reserved].**Source**

The provisions of these §§ 221.44—221.49 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123694) to (123698).

§ 221.50. Facilities using CR or DR.

(a) When exposure indicators are available, the facility shall establish, document and post an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary and results documented.

(b) Facilities shall establish and follow an image QC program in accordance with the recommendations of a QMP, the system manufacturer or a nationally-recognized organization.

(c) Facilities other than dental, podiatric and veterinary shall complete phantom image evaluation using a phantom approved by a QMP, system manufacturer or the Department. The evaluation shall be completed on a quarterly basis and include, at a minimum, all of the following:

- (1) Artifacts.
- (2) Spatial resolution.
- (3) Contrast/noise.
- (4) Workstation monitors.
- (5) Exposure indicator constancy.

(d) In addition to subsections (a)—(c), CR facilities shall erase all CR cassettes, at a minimum, on a weekly basis.

(e) Dental and podiatric facilities shall maintain and operate photostimulable storage phosphor and DDR systems in accordance with manufacturer specifications.

(f) The facility shall maintain records for 5 years for inspection by the Department.

Authority

The provisions of this § 221.50 issued under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of the Administrative Code (71 P.S. § 510.20).

Source

The provisions of this § 221.50 adopted October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791.

§§ 221.51—221.55. [Reserved].**Source**

The provisions of these §§ 221.51—221.55 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123698) to (123701).

§ 221.56. [Reserved].**Source**

The provisions of this § 221.56 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (249304) and (254511).

OTHER SYSTEMS**§ 221.61. Radiation therapy simulation systems.**

(a) Fluoroscopic systems used solely for radiation therapy simulations shall only comply with §§ 221.35a(a) and (b), 221.37a, 221.40a and 221.41a. The requirements in § 221.41a (relating to fluoroscopic timer) may also be satisfied if a means is provided to indicate the cumulative time that an individual patient has been exposed to X-rays. In this case, procedures shall require that the timer be reset between examinations.

(b) CT units used solely for therapy simulations shall comply with §§ 221.202(h)(1), (7) and (8) and 221.203 (relating to equipment requirements; and facility design requirements).

Authority

The provisions of this § 221.61 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.61 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (333943).

§ 221.62. [Reserved].**Source**

The provisions of this § 221.62 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123701) to (123702).

§ 221.63. Therapy imaging guidance systems.

(a) The QMP shall develop QC procedures and tolerances for therapy imaging guidance systems following nationally-recognized standards or those recommended by the manufacturer.

(b) If a system is a CBCT, it must conform to the requirements of § 221.64 (relating to CBCT).

Authority

The provisions of this § 221.63 issued under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of the Administrative Code (71 P.S. § 510.20).

Source

The provisions of this § 221.63 adopted October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791.

§ 221.64. CBCT.

(a) The following radiation measurements shall be evaluated annually and as soon as practical after a component repair or change which, in the opinion of the QMP or QE, may affect the performance of the CBCT unit:

(1) *Beam alignment.* The X-ray field in the plane of the image receptor may not exceed beyond the edge of the image receptor by more than 2% of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the X-ray field must be aligned with the center of the image receptor to within 2% of the SID.

(2) A performance evaluation shall be performed by or under the direct supervision of a QMP or QE. The evaluation shall follow nationally-recognized standards and tolerances or those recommended by the manufacturer. The evaluation shall be performed within 30 days of initial installation, at intervals not to exceed 14 months, and within 30 days after any change or replacement of components which could cause a change in the radiation output or image quality.

(3) The registrant shall document and implement QC guidelines in accordance with nationally-recognized guidelines.

(4) The registrant shall document and implement a policy addressing deviations from established protocols.

(5) In addition to the requirements of § 221.16 (relating to training, competency and continuing education), the CBCT X-ray system shall only be operated by an individual who has been specifically trained in its operation.

(6) The facility shall maintain documentation of the established standards and tolerances and testing results for 5 years for inspection by the Department.

(b) The CBCT operator shall have instructions on all of the following:

(1) Performing routine QC, including the use of the CBCT phantom.

(2) A schedule of routine QC appropriate for the system.

(3) Allowable variations set by the QMP, if required, for the indicated parameters.

(4) The results of at least the most recent routine QC completed on the system.

(c) CBCT systems are exempt from § 221.202(a) (relating to equipment requirements).

Authority

The provisions of this § 221.64 issued under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of the Administrative Code (71 P.S. § 510.20).

Source

The provisions of this § 221.64 adopted October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791.

Cross References

This section cited in 25 Pa. Code § 221.63 (relating to therapy imaging guidance systems).

§ 221.65. X-ray attenuation systems.

CT systems solely used to calculate attenuation coefficients or for image registration in nuclear medicine studies must meet the requirements in §§ 221.202—221.205 unless otherwise exempted as follows:

- (1) CT systems identified in this section are exempt from §§ 221.202(a) and 221.204(a)(4)(xi) (relating to equipment requirements; and performance evaluations, routine QC and surveys).
- (2) Instead of § 221.204(a) (relating to performance evaluations, routine QC and surveys), the registrant shall complete a performance evaluation on the CT system following the recommendations of a QMP, the system manufacturer or a nationally-recognized organization at intervals not to exceed 14 months.
- (3) Instead of § 221.204(b), checks shall be established and documented by the registrant following nationally-recognized guidelines or those recommended by the manufacturer.

Authority

The provisions of this § 221.65 issued under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of the Administrative Code (71 P.S. § 510.20).

Source

The provisions of this § 221.65 adopted October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791.

**THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES
LESS THAN 1 MEV****§ 221.71. Equipment requirements.**

- (a) When the tube is operated at its leakage technique factors, the leakage radiation may not exceed:
 - (1) One hundred milliroentgens (25.8 μ C/kg) per hour at 5 centimeters from the surface of the tube housing assembly for contact therapy systems.
 - (2) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured or installed prior to December 19, 1987.
 - (3) One hundred milliroentgens (25.8 μ C/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured on or after December 19, 1987.
 - (4) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 151 to 500 kVp systems.
 - (5) One-tenth percent of the exposure rate of the useful beam 1 meter from the source for 501 to 999 kVp systems at 1 meter from the source.
- (b) Fixed diaphragms or cones used for limiting the useful beam must provide at least the same protection as required by the tube housing assembly.
- (c) Beam limiting devices may, for the portion of the useful beam blocked by these devices, transmit not more than 5% of the original X-ray beam intensity at the maximum voltage and maximum treatment filter. This requirement does not

apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

(d) The filter system shall be designed so that:

(1) Filters cannot be accidentally displaced from the useful beam at any possible tube orientation.

(2) The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under operating conditions.

(3) A filter is marked as to its material of construction and its thickness. For wedge filters, the wedge factor and wedge angle shall appear on the wedge or wedge tray.

(4) On equipment purchased after January 1, 1971, a filter indication system shall be used on therapy machines using changeable filters. The system must indicate from the control panel the presence or absence of a filter and be designed to permit easy recognition of an added filter in place.

(5) An X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

(e) The tube housing assembly shall be immobilized during stationary treatments.

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

(g) Contact therapy tube housing assemblies shall have a removable shield of at least .5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(h) Systems of greater than 150 kVp manufactured after December 19, 1987, must have a beam monitor system which meets the following requirements:

(1) Not allow irradiation until a preselected value of exposure has been made at the treatment control panel.

(2) Independently terminate irradiation when the preselected exposure has been reached.

(3) Be designed so that, in the event of a system malfunction or electrical power failure or other interruption, the dose administered to a patient prior to the interruption can be accurately determined.

(4) Have a control panel display which maintains the reading until intentionally reset to zero.

(5) Have a control panel display which does not have scale multiplying factors and utilizes a design so that increasing dose is displayed by increasing numbers.

(i) The following apply to timers on the equipment:

(1) A timer shall be provided which has a display at the control panel. The timer must be graduated in minutes and fractions of minutes. The timer must have a preset time selector and an elapsed time indicator.

- (2) The timer must be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the timer to zero.
- (3) The timer must terminate irradiation when a preselected time has elapsed if a dose monitoring system present has not previously terminated irradiation.
- (4) The timer must permit accurate presetting and determination of exposure time as short as 1 second.
- (5) The timer may not permit an exposure if set at zero.
- (6) The timer may not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.
- (j) The control panel, in addition to the displays required in this section, must have:
- (1) An indication of power status.
 - (2) An indication of X-ray production.
 - (3) The means of indicating X-ray tube current and voltage.
 - (4) The means of terminating an exposure.
- (k) When a control panel may energize more than one X-ray tube, the following requirements shall be met:
- (1) It must be possible to activate only one X-ray tube at one time.
 - (2) There must be an indication at the control panel identifying which X-ray tube is energized.
 - (3) There must be an indication at the tube housing assembly when that tube is energized.
- (l) There must be a means of determining the SSD to within 5 millimeters.
- (m) Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.
- (1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.
 - (2) An indication of shutter position must appear at the control panel.
- (n) Electronic brachytherapy devices are exempt from the requirements in subsections (k)—(m).

Authority

The provisions of this § 221.71 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20); and the Radon Certification Act (63 P.S. §§ 2001—2014).

Source

The provisions of this § 221.71 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended May 16, 2008, effective May 17, 2008, 38 Pa.B. 2243; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (333944) to (333946).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); and 25 Pa. Code § 216.3 (relating to exemptions).

§ 221.72. Facility design requirements for systems capable of operating above 50 kVp.

(a) Provision shall be made to permit continuous observation of and communication with the patient during irradiation.

(b) Windows, mirror systems or closed-circuit television viewing screens used for observing the patient shall be so located that the operator can maintain direct surveillance over both the control panel and the patient.

(c) Treatment rooms which contain an X-ray system capable of operating above 150 kVp shall meet the following additional requirements:

(1) Necessary shielding, except for a beam interceptor, shall be provided by fixed barriers.

(2) The control panel shall be outside the treatment room or in a shielded booth.

(3) Doors of the treatment room shall be electrically interlocked to the control panel so that X-ray production cannot occur unless entrance doors are closed.

(4) Interlocks shall be provided so that, when a door of the treatment room is opened, either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than two milliroentgens (.52 $\mu\text{C}/\text{kg}$) per hour and a maximum of ten milliroentgens (2.58 $\mu\text{C}/\text{kg}$) per hour at a distance of 1 meter in any direction from the target; or interlocks shall energize a conspicuous visible or audible alarm signal so that the individual entering and the operator are made aware of the entry. After a shut-off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

(5) Treatment room entrances shall be provided with warning lights, which will indicate when the useful beam is on, in a readily observable position near the outside of access doors.

Authority

The provisions of this § 221.72 issued under section 302 of the Radiation Protection Act (35 P.S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.72 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); and 25 Pa. Code § 216.3 (relating to exemptions).

§ 221.73. Surveys.

(a) A facility shall have a survey made by, or under the direction of, a qualified expert. The survey shall also be done after a change in the facility or equipment which might cause a change in radiation levels.

(b) The qualified expert or radiological physicist shall report the survey results in writing to the individual in charge of the facility and a copy of the report shall be maintained by the registrant for inspection by the Department. The facility shall be operated in compliance with limitations indicated by the survey.

Authority

The provisions of this § 221.73 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.73 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (249309).

§ 221.74. Calibration.

(a) The calibration of an X-ray system shall be performed at intervals not to exceed 1 year and after a change of replacement of components which could cause a change in the radiation output.

(b) The calibration of the radiation output of the X-ray system shall be performed by or under the direction of a qualified expert for radiation therapy calibration who is physically present at the facility during the calibration.

(c) The calibration of the radiation output of an X-ray system shall be performed with a calibrated instrument. The calibration of the instrument shall be traceable to a National standard. The instrument shall have been calibrated within the preceding 2 years.

(d) Calibrations made under this section shall be made so that the dose at a reference point in soft tissue may be calculated as accurately as possible but with an uncertainty of no greater than 5%.

(e) The calibration of the X-ray system shall include, but is not limited to, the following determinations:

(1) The exposure rates for each combination of field size, technique factors, filter and treatment distance used.

(2) The degree of congruence between the radiation field and the field indicated by the localizing device if a device is present.

(3) An evaluation of the uniformity of the largest radiation field used.

(f) Records of calibration performed under this section shall be maintained by the registrant for at least 5 years after completion of the calibration.

(g) A copy of the most recent X-ray system calibration shall be available at the control panel.

Authority

The provisions of this § 221.74 issued under section 302 of the Radiation Protection Act (35 P.S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.74 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249309) to (249310).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 216.3 (relating to exemptions); and 25 Pa. Code § 221.75 (relating to spot checks).

§ 221.75. Spot checks.

Spot checks shall be performed on X-ray systems capable of operation at greater than 150 kVp. The spot checks shall meet the following requirements:

- (1) The procedures shall be in writing and shall have been developed by a qualified expert for radiation therapy calibration.
- (2) If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a radiological physicist within 15 days.
- (3) The measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the X-ray system.
- (4) The spot-check procedure shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in § 221.74 (relating to calibration).
- (5) The procedure shall also note conditions which require that the system be recalibrated under § 221.74.
- (6) Records of spot-check measurements performed under this section shall be maintained by the registrant for 5 years following the measurement.
- (7) Spot check measurements shall be performed using a dosimetry system that has been calibrated under § 221.74(c). Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated under § 221.74(c). The alternative calibration method shall have been performed within the previous year and after each servicing that may have affected the system calibration.

Authority

The provisions of this § 221.75 issued under section 302 of the Radiation Protection Act (35 P.S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.75 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249310) to (249311).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); and 25 Pa. Code § 216.3 (relating to exemptions).

§ 221.76. Operating procedures.

(a) Therapeutic X-ray systems shall be secured to prevent unauthorized use whenever the system is unattended.

(b) If a patient is held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(c) The tube housing assembly may not be held by an individual during exposures.

(d) No individual other than the patient may be in the treatment room during irradiation unless protected by a shielded booth.

(e) Interlocks, on-off beam control mechanisms and safety and warning devices shall be checked and appropriately serviced at least once in a calendar year.

Authority

The provisions of this § 221.76 issued under section 302 of the Radiation Protection Act (35 P.S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.76 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); and 25 Pa. Code § 216.3 (relating to exemptions).

§§ 221.81—221.102. [Reserved].**Source**

The provisions of these §§ 221.81—221.102 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123709) to (123726).

COMPUTED TOMOGRAPHY X-RAY SYSTEMS**§ 221.201. Definitions.**

In addition to the definitions in §§ 215.2 and 221.2 (relating to definitions), the following words and terms, when used in this section and §§ 221.202—221.205, have the following meanings, unless the context clearly indicates otherwise:

Alert value—A dose index value (for example, $CTDI_{vol}$ (mGy) or of DLP (mGy-cm)) that is set by the registrant or licensee, or both, to trigger an alert to the operator prior to scanning within an ongoing examination. The alert value represents a value well above the registrant's or licensee's established range for the examination that warrants more stringent review and consideration before proceeding.

CS—Contrast scale—The change in the linear attenuation coefficient per CT number relative to water; that is:

$$CS = (U_x - U_w) / ((CT)_x - (CT)_w)$$

Where:

U_x = Linear attenuation coefficient of the material of interest

U_w = Linear attenuation coefficient of water

$(CT)_x$ = CT number of the material of interest

$(CT)_w$ = CT number of water

CT—Computed tomography—The production of a tomogram by the acquisition and computer processing of X-ray transmission data.

CT conditions of operation—The selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration and the technique factors as defined in this chapter.

CT dosimetry phantom—The phantom used for determination of the dose delivered by a CT X-ray system.

CT number—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 CTN is used.

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

CTDI—Computed tomography dose index—

(i) The integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan.

$$CTDI = \frac{1}{NT} \int_{-\infty}^{\infty} D(z) dz ,$$

where:

z = Position along a line perpendicular to the tomographic plane.

$D(z)$ = Dose at position z .

T = Nominal tomographic section thickness (cm).

N = Number of tomograms produced in a single scan.

(ii) This definition assumes that the dose profile is centered around $z = 0$ and that, for a multiple tomogram system, the scan increment between adjacent scans is NT.

CTDI₁₀₀—An accumulated multiple scan dose at the center of a 100-mm scan that requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of CTDI₁₀₀, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available “pencil” ionization chamber. CTDI₁₀₀ is acquired using a 100-mm long, 3-cc active volume CT “pencil” ionization chamber, one of the two standard CTDI acrylic phantoms (16 and 32 cm diameter) and a stationary patient table.

CTDI_{vol}—*Volume Computed Tomography Dose Index*—A radiation dose parameter derived from the CTDI_w (weighted or average CTDI given across the field of view), that 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,

$$CTDI_{vol} = (1 / \text{pitch}) \times CTDI_w$$

CTDI_w—*Weighted Computed Tomography Dose Index*—The estimated average CTDI₁₀₀ across the field of view. The equation is:

$$CTDI_w = 1/3 \text{ CTDI}_{100.\text{center}} + 2/3 \text{ CTDI}_{100.\text{edge}}$$

Where 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 cm or 32 cm acrylic phantom. CTDI_w uses CTDI₁₀₀ and an f-factor for air (0.87 rad/R for exposure or 1.0 mGy for air kerma measurements).

Detector—A device that provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Dose profile—The dose as a function of position along a line.

Elemental area—The smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted.

Gantry—The tube housing assemblies, beam-limiting devices, detectors, transformers, if applicable, and the supporting structures and frames which hold these components.

Lux—A unit illumination equivalent to 1 lumen per square centimeter or 0.0929 foot-candles.

Modulation transfer function—The modulus of the Fourier transform of the impulse response of the system.

Multiple tomogram system—A CT X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Noise—The standard deviation of the fluctuations in the CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = 100 \times CS \times S/U_w$$

Where:

CS = Contrast scale

U_w = Linear attenuation coefficient of water.

S = Estimated standard deviation of the CT number of picture elements in a specified area of the CT image.

Nominal tomographic section thickness—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.

Notification value—A dose index value (for example, $CTDI_{vol}$ (mGy) or DLP (mGy-cm)) that is set by the registrant to trigger a notification to the operator prior to scanning when the dose index exceeds the established range for the examination.

Performance phantom—A phantom which has a capability of providing an indication of CS, noise, nominal tomographic section thickness, the resolution capability of the CT system for low and high contrast objects, and measuring the mean CT number for water or other reference materials.

Picture element—See elemental area.

Pixel—See elemental area.

Reference plane—A plane which is at a known fixed distance—which could be zero—to the tomographic plane and parallel to it.

Scan—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—The amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of the displacement.

Scan sequence—A preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Scan time—The period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

Sensitivity profile—The relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

Single tomogram system—A CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

Technique factors—The conditions of operation, specified as follows:

- (i) For CT equipment designed for pulsed operations, peak tube potential, scan time in seconds, X-ray pulse width in seconds and the number of X-ray pulses per second or per mAs.

(ii) For CT equipment not designed for pulsed operation, peak tube potential, and either tube current and scan time in seconds or the product of tube current and exposure time in mAs.

Tomogram—The depiction of the X-ray attenuation properties of a section through a body.

Tomographic plane—The geometric plane which is identified as corresponding to the output tomogram.

Tomographic section—The volume of an object whose X-ray attenuation properties are imaged in a tomogram.

Authority

The provisions of this § 221.201 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20); and amended under the Radon Certification Act (63 P.S. §§ 2001—2014).

Source

The provisions of this § 221.201 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended May 16, 2008, effective May 17, 2008, 38 Pa.B. 2243; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (333947) to (333950).

§ 221.202. Equipment requirements.

(a) *Accreditation.* All diagnostic CT X-ray systems must be accredited by an accrediting organization recognized by the Department within 1 year from first patient use.

(b) *Technical and safety information.* The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer shall be maintained by the facility and readily accessible to the operators.

(c) *Termination of exposure.* The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under X-ray system control, of greater than 0.5 second duration. Termination of the X-ray exposure shall necessitate resetting of the conditions of operation prior to initiation of another scan.

(d) *Tomographic plane indication and alignment.*

(1) For any single tomogram system, a means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, a means shall be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic plane.

(e) *Status indicators and control switches.*

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(2) The emergency buttons or switches shall be clearly labeled as to their function.

(3) Each individual scan or series of scans shall require initiation by the operator.

(f) *Indication of CT conditions of operation.* The CT X-ray system shall be designed so that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(g) *Leakage radiation.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(h) *Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.*

(1) The total error in the indicated location of the tomographic plane or reference plane by the light field or laser indicator may not exceed 5 millimeters.

(2) If the X-ray production period is less than 0.5 second, the indication of X-ray production shall be actuated for at least 0.5 second. Beam-on and shutter status indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The CT X-ray system shall be normalized to water.

(4) The CT number for water for a region of interest, not exceeding 100 square millimeters, shall be 0 ± 7.0 CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the QMP, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the QMP may establish and maintain an equivalent value.

(5) With the performance phantom, the mean CT number of water of one group of pixels may not differ from the mean CT number of water of a second group of pixels equal size within the same image by more than the manufacturer's published specifications, or those established by the QMP.

(6) The noise, utilizing the facility's performance phantom, may not exceed the manufacturer's published specifications.

(7) The total error between the indicated and actual slice thickness may not exceed 2.0 millimeters.

(8) A distance of at least 100 millimeters measured in a CT image shall agree with the actual distance to within $\pm 5\%$.

(9) Premature termination of the X-ray exposure by the operator shall necessitate resetting the CT conditions of operation prior to the initiation of another scan.

Authority

The provisions of this § 221.202 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.202 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (333950) and (304519) to (304520).

Cross References

This section cited in 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems); 25 Pa. Code § 221.64 (relating to CBCT); 25 Pa. Code § 221.65 (relating to X-ray attenuation systems); 25 Pa. Code § 221.201 (relating to definitions); and 25 Pa. Code § 223.31 (relating to registrant responsibilities).

§ 221.203. Facility design requirements.

(a) *Oral communication.* Provision shall be made for oral communication between the patient and the operator at the control panel.

(b) *Viewing systems.*

(1) A means shall be provided to permit continuous observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

(2) If the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

Authority

The provisions of this § 221.203 issued under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.203 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems); 25 Pa. Code § 221.65 (relating to X-ray attenuation systems); 25 Pa. Code § 221.201 (relating to definitions); and 25 Pa. Code § 223.31 (relating to registrant responsibilities).

§ 221.204. Performance evaluations, routine QC and surveys.

(a) *Performance evaluations.*

(1) The performance evaluation of the CT X-ray system shall be performed by or under the direction of a QMP.

(2) Evaluation standards and tolerances shall be established by a QMP and maintained by the facility. These standards and tolerances must meet nationally-recognized standards and tolerances for the CT X-ray system.

(3) The performance evaluation of a CT X-ray system shall be performed after initial installation and before use on human patients. Thereafter, the evaluation shall be made at intervals not to exceed 14 months.

(4) The performance evaluation must include all of the following:

(i) Geometric factors and alignment, including alignment light accuracy and table incrementation accuracy.

(ii) Slice localization from scanned projection radiograph (localization image).

(iii) Slice thickness.

(iv) Image quality including high-contrast (spatial) resolution, low-contrast resolution, image uniformity, noise and artifact evaluation.

(v) CT number accuracy.

(vi) Image quality for acquisition workstation display devices (video and hard copy when applicable).

(vii) A review of the results of the routine QC required under subsection (b).

(viii) A safety evaluation of audible and visual signals and posting requirements.

(ix) A review of commonly used CT protocols along with the evaluation for appropriateness of dose and image quality, in comparison with the older protocols. The review should be by the QMP along with the radiologist and lead CT technologist.

(x) For dosimetry, a review of the protocols deemed appropriate by the QMP which could result in significant doses. This review must include acquisition and reconstruction parameters, and radiation dose. At a minimum, the QMP shall review the following clinical protocols, if performed, at intervals not to exceed 14 months:

(A) Pediatric head (1 year of age).

(B) Pediatric abdomen (5 years of age; 40—50 lbs. (about 20 kg)).

(C) Adult head.

(D) Adult abdomen (70 kg).

(E) Brain perfusion.

(xi) Review DRL, notification values and alert values for the procedures reviewed under subparagraph (x).

(xii) Review actions to be taken when a dose alert value is exceeded including patient follow-up.

(xiii) Review the process determining who has access and authority to make changes to the protocol management systems, including a policy or procedure to prevent inadvertent or unauthorized modifications to a CT protocol.

(5) A performance evaluation shall be made within 30 days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality.

(6) Dose measurements of a CT unit shall be performed with a calibrated dosimetry system. The calibration of the system shall be traceable to a national standard. The dosimetry system must have been calibrated within the preceding 2 years.

(b) *Routine QC.*

(1) Written routine QC procedures shall be developed by a QMP. These procedures shall be available for review by the Department.

(2) The routine QC procedures must include, at a minimum, all of the following using the facility's performance phantom:

- (i) Noise.
- (ii) Mean CT number for water.
- (iii) Artifact evaluation.

(3) The routine QC shall be performed at intervals not to exceed 1 week.

(4) The QMP need not be present during the routine QC.

(5) Routine QC shall include acquisition of images obtained with the performance phantom using the same processing mode and CT conditions of operation as are used to perform the measurements required by subsection (a).

(c) *Radiation protection surveys.*

(1) CT X-ray systems shall have a survey performed at the time of installation by or under the direction of a QMP. In addition, a survey shall be performed after a change in the facility or equipment which might cause a significant increase in radiation hazard.

(2) The registrant shall obtain a written report of the survey from the QMP, and a copy of the report shall be made available to the Department upon request.

(d) *Records.* Records of the performance evaluations and surveys shall be maintained for inspection by the Department for at least 5 years. Routine QC records shall be maintained for at least 1 year.

Authority

The provisions of this § 221.204 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.204 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (304520) to (304522).

Cross References

This section cited in 25 Pa. Code § 221.65 (relating to X-ray attenuation systems); 25 Pa. Code § 221.201 (relating to definitions); and 25 Pa. Code § 223.31 (relating to registrant responsibilities).

§ 221.205. Operating procedures.

(a) In addition to the training requirements in § 221.16 (relating to training, competency and continuing education), a CT X-ray system shall be operated only by an individual who has been specifically trained in its operation.

(b) All of the following information must be readily available to the CT operator:

(1) Instructions on the use of the CT phantoms and a process for reporting deviations in protocols including a schedule of routine QC appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent performance evaluation conducted on the system.

(2) Current protocol information available at the control panel which specifies for each routine examination the CT conditions of operation.

(c) If the radiation measurements and performance evaluation of the CT X-ray system indicates that a system operating parameter has exceeded a tolerance established by the QMP, the use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the QMP.

Authority

The provisions of this § 221.205 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this § 221.205 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (304522) to (304523).

Cross References

This section cited in 25 Pa. Code § 221.65 (relating to X-ray attenuation systems); 25 Pa. Code § 221.201 (relating to definitions); and 25 Pa. Code § 223.31 (relating to registrant responsibilities).

APPENDIX A
DETERMINATION OF COMPETENCE

The registrant shall ensure that individuals who operate diagnostic X-ray equipment have received training on the subjects listed in this appendix. The individual shall be trained and competent in the general operation of the X-ray equipment, and in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

- (1) Basic properties of radiation.
- (2) Units of measurement.
- (3) Sources of radiation exposure.
- (4) Methods of radiation protection.
- (5) Biological effects of radiation exposure.
- (6) X-ray equipment.
- (7) Image recording and processing.
- (8) Patient exposure and positioning.
- (9) Procedures.
- (10) Quality assurance.
- (11) Regulations.

Authority

The provisions of this Appendix A issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P.S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20).

Source

The provisions of this Appendix A adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (249320).

Cross References

This appendix cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities); 25 Pa. Code § 223.31 (relating to registrant responsibilities); and 25 Pa. Code § 228.35 (relating to operating procedures).

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