Physicians Review Guide for Safe Use of Medical Fluoroscopy

INTRODUCTION:

The purpose of this guide is to satisfy the Commonwealth of Pennsylvania, Title 25, Environmental Protection Standards. Under section 221.11 Administrative Controls, Registrant responsibilities.

§ 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.

APPENDIX A
DETERMINATION OF COMPETENCE

The registrant shall ensure that training on the subjects listed in Appendix A has been conducted. 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 procedure(s) 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) Imaging Recording and Processing
(8) Patient Exposure and Positioning
(9) Procedures
(10) Quality Assurance Program
(11) Regulations

Reference: 25 PA code part 221.11 Registrant responsibilities.

Section 1 – Basic Properties of Radiation used in Medicine

Medical Radiation, including the use of Fluoroscopy, falls into the category of Ionizing Radiation.
Ionization is the process in which a charged portion of a molecule (usually an electron) is given enough energy to break away from the atom. This process results in the formation of two charged particles or ions: the molecule with a net positive charge and the free electron with a negative charge.
Higher frequency ultraviolet radiation begins to have enough energy to break chemical bonds.
X-ray and gamma ray radiation, which are at the upper end of magnetic radiation, have very high frequencies (in the range of 100 billion billion Hertz) and very short wavelengths of about 1 picometer (1 trillionth of a meter). Radiation in this range has extremely high energy. It has enough energy to strip off electrons or, in the case of very high-energy radiation, break up the nucleus of atoms.

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Each ionization releases approximately 33 electron volts (eV) of energy. Material surrounding the atom absorbs the energy. Compared to other types of radiation that may be absorbed, ionizing radiation deposits a large amount of energy into a small area. In fact, the 33 eV from one ionization is more than enough energy to disrupt the chemical bond between two carbon atoms. All ionizing radiation is capable, directly or indirectly, of removing electrons from most molecules.

There are three main kinds of ionizing radiation:

- alpha particles, which include two protons and two neutrons
- beta particles, which are essentially high-speed electrons
- gamma rays and x-rays, which are pure energy (photons).

Source: http://www.epa.gov/radiation/understand/index.html

Section 2 – Units of Measurement

There are three (3) quantities and their units to be most familiar with. They are exposure, absorbed dose and dose equivalent.

Exposure: The quantity of x-rays or gamma radiation required to produce an amount of ionization in air at standard temperature and pressure. The traditional unit is the Roentgen (R) and the SI unit is defined as coulombs/kilogram or (C/Kg) Radiation survey meters most often measure exposure in Roentgen per hour (R/hr) or milliroentgen per hour (mR/hr). Fluoroscopic output is measured in R per minute (R/min)

Absorbed Dose: Absorbed dose is defined as the amount of ionizing radiation energy absorbed per unit mass. The associated unit is known as the rad (radiation absorbed dose) and 1 rad = 1 Joule/Kg. The SI unit of absorbed dose is the Gray (Gy), and 1 Gy = 100 rad. For general fluoroscopic exposures, using 1 R results in and absorbed dose of 1 rad.

Dose Equivalent: This is the radiation safety term to account for differences in the biological effectiveness of the different types of ionizing radiation. Dose equivalent is the absorbed dose times a radiation quality factor. For x-rays including fluoroscopic procedures the quality factor is 1. The unit for dose equivalent is the rem (Roentgen equivalent man) and the SI unit is the Sievert (Sv). 1 Sv = 100 rem

Radiation Unit Conversion Factors
Unit of measure
Conversion equivalent

1 curie = 3.7 x 1010 disintegrations/second
1 becquerel = 1 disintegration/second
1 millicurie (mCi) = 37 megabecquerels (MBq)
1 rad = 0.01 gray (Gy)
1 rem = 0.01 sievert (Sv)
1 roentgen (R) = 0.000258 coulomb/kilogram (C/kg)
1 megabecquerel (MBq) = 0.027 millicuries (mCi)
1 gray (Gy) = 100 rad
1 sievert (Sv) = 100 rem
1 coulomb/kilogram (C/kg) = 3880 roentgens

Adapted from Measurement - Activity: How Much Is Present? (Radiation Emergency Assistance Center/Training Site (REAC/TS))

Source: http://orise.orau.gov/reacts/guide/measure.htm

Section 3 Sources of Radiation Exposure:

We can't get away from background radiation…it's everywhere! 82% of radiation exposure comes from natural radiation and 18% is man-made. Man-made sources include X-rays from medical procedures, nuclear medicine products for medical diagnostics, and consumer products such as building materials.

Medical imaging has led to improvements in the diagnosis and treatment of numerous medical conditions in children and adults.

There are many types - or modalities - of medical imaging procedures, each of which uses different technologies and techniques. Computed tomography (CT), fluoroscopy, and radiography ("conventional X-ray" including mammography) all use ionizing radiation to generate images of the body. As above, ionizing radiation is a form of radiation that has enough energy to potentially cause damage to DNA and may elevate a person's lifetime risk of developing cancer.

CT, radiography, and fluoroscopy all work on the same basic principle: an X-ray beam is passed through the body where a portion of the X-rays are either absorbed or scattered by the internal structures, and the remaining X-ray pattern is transmitted to a detector (e.g., film or a computer screen) for recording or further processing by a computer. These exams differ in their purpose:

Radiography - a single image is recorded for later evaluation. Mammography is a special type of radiography to image the internal structures of breasts.
Fluoroscopy - a continuous X-ray image is displayed on a monitor, allowing for real-time monitoring of a procedure or passage of a contrast agent ("dye") through the body. Fluoroscopy can result in relatively high radiation doses, especially for complex interventional procedures (such as placing stents or other devices inside the body) which require fluoroscopy be administered for a long period of time.
CT - many X-ray images are recorded as the detector moves around the patient's body. A computer reconstructs all the individual images into cross-sectional images or "slices" of internal organs and tissues. A CT exam involves a higher radiation dose than conventional radiography because the CT image is reconstructed from many individual X-ray projections.

http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandprocedures/medicalimaging/medicalx-rays/default.htm#principles

Section 4 – Risk Reduction Techniques – Recommendations:

1. Ensure that the Fluoroscopy unit has had a preventative maintenance inspection by a qualified service engineer and an image quality/radiation safety survey performed by a qualified Medical Physicist at least annually.
2. Minimize the amount of fluoro "on" time.
3. Maximize the use of "last image hold".
4. Use good "geometry", ie position the patient as close to the image intensifier and as far from the x-ray tube as possible
5. Select the lowest dose rate (highest kV / lowest mA combination) ABC setting that gives acceptable image quality
6. Minimize the use of boost and MAG modes.
7. Always collimate down to the anatomical region of interest.
8. On equipment that has pulsed fluoroscopy, use the lowest pulse rate consistent with acceptable temporal resolution.
9. On equipment that has fluoro frame averaging, use the highest number of frames to be averaged consistent with acceptable temporal resolution.
10. When long fluoro times are anticipated for a single procedure (>20 min), vary the x-ray tube angle (to the extent possible) to reduce the skin dose to any one area. This is especially important for larger patients.
11. Stand as far as possible from the point where the x-ray beam enters the patient.
12. Minimized the placement of hands in the patient exit beam. Never place your hands in the patient entrance beam without 0.5 mm thick lead gloves.
13. Always wear a lead apron or stand behind a lead barrier whenever you are in a room where fluoroscopy is being performed.
14. Even if you are wearing a lead apron, position any additional lead shielding between the patient and your face/neck.
15. For lateral or large angle oblique views, stand on the same side of the table as the image intensifier.
16. Always wear your radiation badge(s) where fluoroscopy is being performed.
    - primary badge is to be worn at collar level outside your lead apron.
    - If a second badge is issued, wear it at waist level underneath any lead apron
    - If your work involves placing you hands in close proximity to the x-ray field, request and wear a ring badge.

Section 5 - Biological effects of Radiation Exposure

There are two (2) General categories:
1. Deterministic risk: Radiation induced skin burns, hair loss, sterility, cataracts.

- Skin damage thresholds can potentially be reached in under 20 minutes of standard fluoroscopy.
- For very large patients, entrance exposure rates increase exponentially with patient thickness.
- Risk of damage increases when there are multiple fluorography runs.

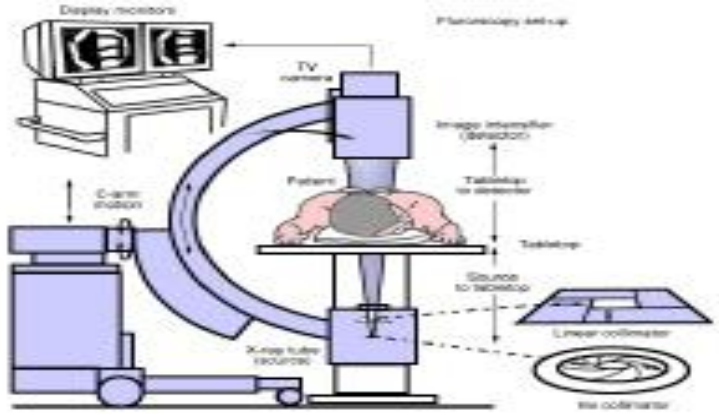
Effect	Threshold (rad)	Hours of Fluoro On-Time, 5 R/min	Hours of Cine On-Time, 30 R/min	Time to onset of effect
Transient Erythema	200	0.7	0.1	24 hr
Epilation	300	1	0.2	3 wk
Erythema	600	2	0.3	10 day
Pericarditis	800	2.7	0.4	>10 wk
Dermal Necrosis	1800	6	1	>10 wk
Skin Cancer	None Known	N/A	N/A	> 5 yr.

2. Stochastic risk: (Cancer and genetic defects)
   - Although stochastic risks may be small for any one individual, it is a matter of greater significance on an epidemiological scale.
   - Radiation induced cancers and genetic defects cannot be distinguished from those that appear spontaneously.
   - There is direct epidemiological evidence for increased radiation induced cancer risk in humans for organ doses above approximately 0.1 – 0.15 Gy (10 – 15 rads) from the atomic bomb survivors.
   - At lower doses the statistical uncertainties in the data are too large to support a particular radiation risk vs. dose model, including the possibility of a "threshold dose" below which the risk is zero.
   - Below approximately 0.1 Gy (10 rads) dose levels, stochastic effects are believed to be masked (statistically) by the high incidence of spontaneous cancers and birth defects in the general population.
   -

Source: International Commission on Radiological Protection (ICRP) Publication 99, "Low-dose Extrapolation of Radiation-related Cancer Risk," Elsevier, 2006

Section 6 – X-Ray equipment (Fluoroscopy)

Fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor, much like an X-ray movie. During a fluoroscopy procedure, an X-ray beam is passed through the body. The image is transmitted to a monitor so the movement of a body part or of an instrument or contrast agent ("X-ray dye") through the body can be seen in detail.



Fluoroscopy is used in a wide variety of examinations and procedures to diagnose or treat patients. Some examples are:

- Barium X-rays and enemas (to view the gastrointestinal tract)
- Catheter insertion and manipulation (to direct the movement of a catheter through blood vessels, bile ducts or the urinary system)
- Placement of devices within the body, such as stents (to open narrowed or blocked blood vessels)
- Angiograms (to visualize blood vessels and organs)
- Orthopedic surgery (to guide joint replacements and treatment of fractures)

The radiation dose the patient receives varies depending on the individual procedure. Fluoroscopy can result in relatively high radiation doses, especially for complex interventional procedures (such as placing stents or other devices inside the body) which require fluoroscopy be administered for a long period of time.

Sources: emedicine.medscape.com

http://www.epa.gov/radiation/understand/index.html

Section 7 – Image Recording and processing

Digital imaging is an ***essential*** part of fluoroscopic and angiographic systems
• Limitations and advantages of fluoro digital acquisition and processing must be understood for maximum utilization
• DICOM standards are a must for the integration of digital fluoroscopy in the clinical environment and PACS

Fluoroscopic / Fluorographic image processing can provide
– Significant improvement of image quality
– Reduced dose (radiation and contrast)
– Enhanced image details
– DSA, roadmapping, quantitative densitometry
  – Functional imaging, cone-beam fluoro CT

Reduce radiation dose through image averaging
• Enhance conspicuity of clinical information
• Provide quantitative capabilities
• Optimize image display on monitors

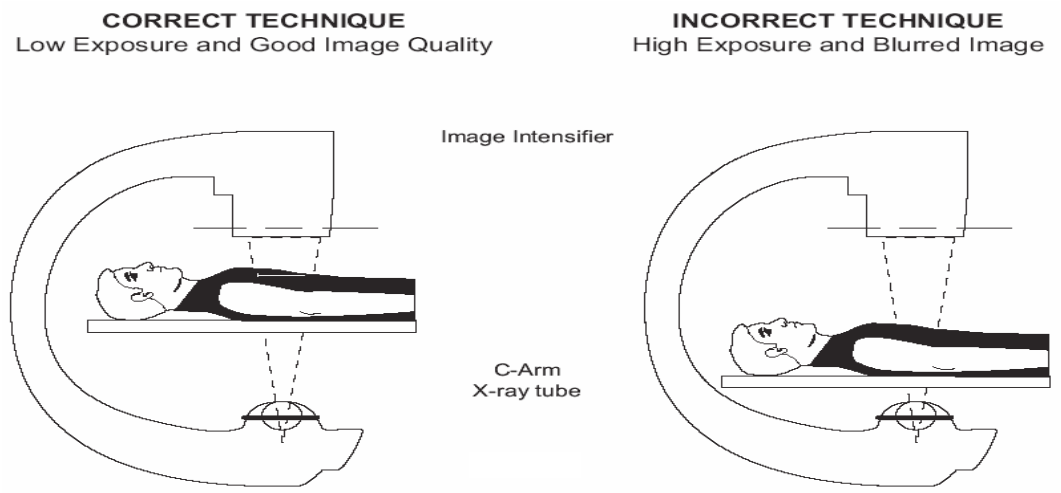
Advantages
– Separation of acquisition and display
– Image processing applications
  – Electronic display, distribution, archive

Positive:
– Image processing and manipulation
– Electronic distribution, display and archive
– Quantitative data analysis

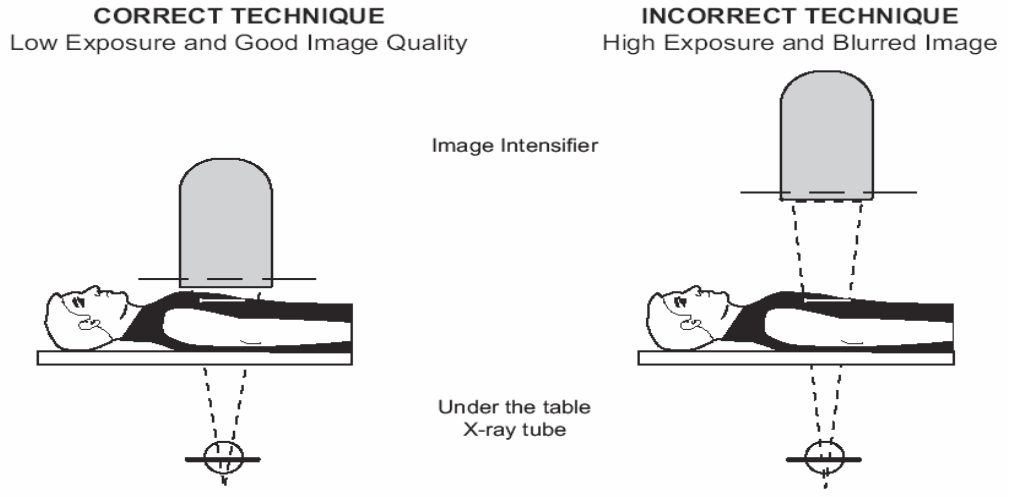
https://www.aapm.org/meetings/03AM/pdf/9834-13948.pdf

Section 8 – Patient exposure and positioning.

1. **Maximize distance between the X ray tube and the patient to the extent possible**



2. Minimize distance between the patient and the image receptor



3. Avoid exposing the same area of the skin in different projections. Vary the beam entrance port by rotating the tube around the patient

Larger patients or thicker body parts trigger an increase in entrance surface dose (ESD)

7. Oblique projections also increase ESD
Be aware that increased ESD increases the probability of skin injury
Source:
http://rpop.iaea.org

Section 9 – Procedures.

Typical Effective Radiation Dose from Diagnostic X Ray—Single Exposure

(Mettler 2008) Exam	**Effective Dose** mSv (mrem)
Chest	0.1 (10)
Cervical Spine	0.2 (20)
Thoracic Spine	1.0 (100)
Lumbar Spine	1.5 (150)
Pelvis	0.7 (70)
Abdomen or Hip	0.6 (60)
Mammogram (2 view)	0.36 (36)
Dental Bitewing	0.005 (0.5)
Dental (panoramic)	0.01 (1)
DEXA (whole body)	0.001 (0.1)
Skull	0.1 (10)
Hand or Foot	0.005 (0.5)

The following table shows the dose a patient could receive if undergoing an entire procedure that may be diagnostic or inter-ventional. For example, a lumbar spine series usually consists of five x-ray exams. (Mettler 2008) Examinations and Procedures	**Effective Dose** mSv (mrem)
Intravenous Pyelogram	3.0 (300)
Upper GI	6.0 (600)
Barium Enema	7.0 (700)
Abdomen Kidney, Ureter, Bladder (KUB)	0.7 (70)
CT Head	2.0 (200)
CT Chest	7.0 (700)
CT Abdomen/Pelvis	10.0 (1,000)
Whole-Body CT Screening	10.0 (1,000)
CT Biopsy	1.0 (100)
Calcium Scoring	2.0 (200)
Coronary Angiography	20.0 (2,000)
Cardiac Diagnostic & Intervention	30.0 (3,000)
Pacemaker Placement	1.0 (100)
Peripheral Vascular Angioplasties	5.0 (500)
Noncardiac Embolization	55.0 (5,500)
Vertebroplasty	16.0 (1,600)

Section 10 – Quality Assurance

Information for the imaging team

Patient radiation dose is considered to be optimized when images of adequate quality for the desired clinical task are produced with the lowest amount of radiation considered to be reasonably necessary. A facility can use its quality assurance (QA) program to optimize radiation dose for each kind of X-ray imaging exam, procedure, and medical imaging task it performs. Patient size is an important factor to consider in optimization, as larger patients generally require a higher radiation dose than smaller patients to generate images of the same quality.

Note that there may be a range of optimized exposure settings, depending on the capabilities of the imaging equipment and the image quality requirements of the physician. Radiation exposure may be optimized properly for the same exam and patient size at two facilities (or on two different models of imaging equipment) even though the radiation exposures are not identical.

One important aspect of a QA program entails routine and systematic monitoring of radiation dose and implementation of follow-up actions when doses are considered to be anomalously high (or low). Here are the rudiments of QA dose monitoring and follow-up:

Recording of modality specific dose indices, associated equipment settings, and patient habitus, obtained, for example, from data of the DICOM radiation dose structured report. [As a modality-specific example, CT dose indices are standardized as CTDIvol and dose-length product (DLP), and they are based on measurements in standardized dosimetry phantoms. In fluoroscopy, typical dose indices include reference air kerma and air kerma-area product.]

Identification and analysis of dose-index values and conditions that consistently deviate from corresponding norms.

Investigative follow-up of circumstances associated with such deviations.

Adjustments of clinical practice and/or protocols to reduce (or possibly increase) dose, if warranted, while maintaining images of adequate quality for diagnosis, monitoring, or interventional guidance.

Periodic reviews with respect to updating current norms or adopting new norms. Reviews can be based on practice trends over time, equipment operator or medical practitioner performance, or authoritatively established dose-index values associated with the most common exams and procedures.

http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandprocedures/medicalimaging/medicalx-rays/default.htm#physician

Section 11 – Regulations (included for reference. See below.)

025 Pa. Code § 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.
(c) A chart, 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. This chart 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 film 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; image recording, processing and viewing; and maintenance and modifications to the quality assurance program. Records shall be maintained by the registrant for inspection by the Department for 3 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 hand-held during the exposure.

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. Immediately preceding text appears at serial pages (249282), (285667) to (285669).

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).