Fluoroscopy
Patient Safety
FLUOROSCOPY SAFETY

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive identifies the required safety standards for the use of fluoroscopic imaging equipment for diagnosis, localization, and guidance as part of interventional procedures. The directive sets forth related policy, procedures, and requirements for implementing such standards. These standards aim to ensure optimal image quality with minimum radiation exposure to patients, health care workers and members of the public.

2. SUMMARY OF MAJOR CHANGES: Major changes include:
   
a. Incorporating VHA Handbook 1105.04 into this directive.

b. Updating definitions and references.

c. Defining different levels of supervision.

d. Incorporating and conforming to current recommendations of professional societies and expert advisory bodies.

e. Updating the responsibilities section to include updated criteria for physicists’ inspection of x-ray equipment following repair services or modifications.

f. Training requirements for fluoroscopic procedures.


4. RESPONSIBLE OFFICE: The Office of the National Director, Radiology Program, Diagnostic Services (10P11D), and the National Health Physics Program (10P11X) are responsible for the contents of this directive. Questions may be referred to 919-384-8593 for the Radiology Program, Diagnostic Services.


6. RECERTIFICATION: This VHA directive is scheduled for recertification on, or before the last working day of June 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.
NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

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FLUOROSCOPY SAFETY

1. PURPOSE

This Veterans Health Administration (VHA) directive defines safety standards for the use of fluoroscopic imaging equipment for diagnostic purposes and interventional procedures to minimize the occurrence of radiation injuries and the risk of cancer, and to ensure a uniform safety standard throughout VHA medical facilities where fluoroscopy is utilized. This directive also establishes related policy, procedures, and responsibilities for implementing such safety standards. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

a. Fluoroscopic imaging is an integral part of health care and is used by many services in a medical facility. A fluoroscope generates a beam of x-rays that is directed through the patient onto a receptor to create real-time images. Fluoroscopes can deliver a large radiation dose to the patient, as well as a significant radiation dose to the operator and other staff near the machine. Large doses of ionizing radiation are known to increase the incidence of cancer. Very large doses have caused skin burns, non-healing ulcers, and other tissue injuries to patients. In order to minimize the occurrence of radiation injuries and the risk of cancer, and to ensure a uniform standard of care throughout VHA, this Directive sets standards for the use of fluoroscopes.

b. The U.S. Occupational Safety and Health Administration (OSHA) regulates the safety of employees from radiation from machine sources at federal facilities. See Title 29 Code of Federal Regulations (CFR) 1910.1096.

3. DEFINITIONS

a. **Air Kerma Area Product.** Air kerma area product, also known as the dose area product, is a measure of air kerma multiplied by the cross-sectional area of the x-ray beam.

b. **As Low As Reasonably Achievable (ALARA).** ALARA means maintaining exposures to ionizing radiation to as low as is reasonably achievable, economic and social factors being taken into account.

c. **Backscatter.** Backscatter is the scattering of radiation back to the direction from which it came.

d. **Cinefluorography.** Fluoroscopy method to continuously record images of the internal anatomical structures of the human body.

e. **Cumulative Air Kerma at the Reference Point.** Also known as reference point air kerma and reference air kerma. It is the air kerma at a defined reference point in the center of the x-ray beam, intended to approximate the location of the skin of an average sized patient. It is displayed by all fluoroscopes manufactured since June 10, 2006.
accumulates during a procedure and can be used to estimate skin dose to the patient, although the peak skin dose and air kerma at the reference point may differ significantly. **NOTE:** Reference point locations are specified according to the type of fluoroscope and consistent with the definition found in 21 CFR 1020.32-Fluoroscopic Equipment.

f. **Diagnostic Radiological Physicists.** Diagnostic radiological physicists must be certified by the American Board of Radiology or have similar qualifications. Diagnostic radiological physicists perform acceptance testing and routine annual testing of diagnostic x-ray equipment to ensure an optimal balance between image quality and radiation exposure. Diagnostic radiological physicists design shielding for rooms housing x-ray imaging equipment and perform shielding acceptance surveys.

g. **Dosimeter.** A dosimeter is a device that measures an absorbed dose of ionizing radiation, often referred to as a film badge.

h. **Fluoroscopic Operator.** There are two types of Fluoroscopic Operator

1. Supervising Fluoroscopic operator – the appropriately trained and credentialed Physician, podiatrist, Nurse Practitioner, or Physicians Assistants who perform or supervise fluoroscopy.

2. Non-supervising fluoroscopic operator – the appropriately trained diagnostic technologists Catheterization Medical Instrument Technician or registered nurse who perform fluoroscopy.

i. **Fluoroscopy.** Fluoroscopy is an imaging technique that uses an x-ray imaging system to provide real-time x-ray projection images.

j. **Gray (Gy).** One Gy is a unit of absorbed dose and is equal to 1 joule per kilogram (1J/kg).

k. **Kerma (K)/ Air Kerma.** K is a quantity defined by the International Commission on Radiation Units and Measurements. K is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in units of joules, in a mass of material expressed in units of kilograms, where the special name for the unit of K is Gy. When the material is air, the quantity is referred to as “air kerma.”

I. **Licensed Individual Practitioner (LIP).** A Licensed Individual Practitioner is one who is authorized to practice with defined levels of autonomy and exercise independent decision making within their scope of practice.

m. **Medical Health Physicists.** Medical health physicists must be certified by the American Board of Medical Physics (ABMP), the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Health Physics (ABHP), or have similar qualifications. Diagnostic Medical Health Physicists may serve as Medical Health Physicist and often as the facility’s Radiation Safety Officer (RSO); they are specialists in radiation safety, which includes safe transport, custody, use, and disposal of radionuclides; inspections and area monitoring; and personal dosimetry. Medical health
physicists protect staff, patients, and the public from ionizing radiation, and provide education in the safe use of x-ray producing equipment.

n. **Medical Physicist.** A medical physicist is a physicist working in medicine. Three medical physics specialties that may be involved in fluoroscopy are: diagnostic radiological physicists, therapeutic radiological physicists, and medical health physicists.

o. **Peak Skin Dose.** The peak skin dose is the largest dose imparted to the skin and takes into account dose from x-rays backscattered in the patient.

p. **Potentially-High Radiation Dose Procedure.** A potentially-high radiation dose procedure is a fluoroscopically-guided procedure with the potential to cause a clinically-significant radiation skin injury. It can be formally defined as a fluoroscopically-guided procedure for which more than 5% of cases of that procedure result in a cumulative air kerma exceeding 3 Gy or an air-kerma-area product exceeding 300 Gy cm².

q. **Qualified Expert.** A qualified expert is a medical physicist or medical health physicist who is competent to design radiation shielding in medical x-ray facilities and may perform shielding calculations and radiation surveys after installation but before clinical use of the equipment.

r. **Rad.** A rad is a traditional unit of absorbed dose, equal to 0.01 J/kg of matter. One hundred rad is equal to a Gy.

s. **Radiation Safety Officer.** The individual designated the responsibility to oversee the day to day operations of the facility radiation safety program, which includes radioactive materials and machine producing ionizing radiation.

t. **Rem.** A rem is a traditional unit of effective dose and effective dose equivalent, equal to 10 millisieverts (mSv). Rem and sievert (Sv) are units of dose that are used when describing the biological effects of radiation in terms of risk.

u. **Sievert (Sv).** A Sv is unit of effective dose and effective dose equivalent. Like Gy, it measures absorbed radiation; Sv is corrected for the carcinogenic risk of the tissues that have been exposed.

v. **Structural Shielding.** Structural shielding is shielding provided by a building’s structure (e.g., concrete walls and floors), or that is installed (e.g., lead sheets installed in walls) as necessary to maintain doses to persons in adjacent areas ALARA and within regulatory limits. The design of shielding for and acceptance testing surveys of imaging rooms must conform to National Council on Radiation Protection and Measurements (NCRP) Report No. 147. The shielding design calculations, as-built shielding plans, and the report on the acceptance testing of the structural shielding must be kept for the duration of use of the room for x-ray imaging.

w. **Substantial Radiation Dose Level (SRDL).** An SRDL is defined as a peak skin dose of 3Gy or, if the peak skin dose is not known, a reference point air kerma of 5Gy. It is a level of radiation dose to a patient that, if exceeded, triggers specific follow-up
actions. The exceedance of an SRDL must cause notification of the patient and follow-up regarding a possible clinically-significant radiation injury. It does not indicate that such an injury will occur or is highly likely. NOTE these match SIR guidelines and NCRP report 168.

x. Supervision of Fluoroscopy Procedures. This term is defined by three levels of supervision and consistent with 42 CFR 410.32, as follows:

(1) General Supervision. The service is furnished under the overall direction and control of the fluoroscopic physician, but his or her physical presence is not required during the procedure.

(2) Direct Supervision. The fluoroscopic physician must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure. “Immediately available” means "interruptible and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary." The physician does not have to be in the room when the procedure is performed.

(3) Personal Supervision. The fluoroscopic physician is present in the room when the service is being performed. The supervisory responsibility is more than the capacity to respond to an emergency. It includes the ability to take over performance of a procedure and to change a procedure or the course of care for a particular patient.

4. POLICY

It is VHA policy that all Veterans receiving fluoroscopic imaging receive the highest quality imaging service, and that both the Veteran receiving and the health care employees performing the fluoroscopic imaging receive minimal radiation exposures that are as low as reasonably achievable (ALARA).

5. RESPONSIBILITIES

a. Under Secretary for Health. The Under Secretary for Health is responsible for ensuring compliance with this directive.

b. Deputy Under Secretary of Health for Operations and Management. The Deputy Under Secretary of Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISN) Directors.

(2) Ensuring that each VISN Director has the resources required to comply with this directive in all VA medical facilities within that VISN.

(3) Overseeing VISN and VA medical facility compliance with this directive and all applicable fluoroscopy standards and Federal regulations.
c. National Director, Radiology Program, Diagnostic Services. The National Director, Radiology Program, Diagnostic Services, is responsible for coordination with NHPP to evaluate changes in accrediting agencies or when technological changes in fluoroscopy would necessitate a change to the directive.

d. The National Radiation Safety Committee. The NRSC is responsible for tracking all sentinel events that are related to radiation safety, including events related to improper use of fluoroscopy. This tracking takes the form of meeting minutes from the reoccurring meeting between the NRSC and the National Health Physics Program (NHPP). In each quarterly meeting, the NHPP reports when sentinel events are initially discovered, as well as any updates about the status of ongoing sentinel events, until they are resolved.

e. National Director, National Health Physics Program. The NHPP National Director is responsible for:

(1) Coordinating with National Radiology Program (NRP) to evaluate changes in standards of accrediting agencies or when technological changes in fluoroscopy would necessitate a change to the directive.

(2) Investigating radiation related injuries to patients when notified of patient injuries.

(3) Reporting patient sentinel events and injuries that required surgical repair to the National Radiation Safety Committee (NRSC).

(4) Implementing the radiation protection compliance oversight program for machine sources of ionizing radiation to include: Issuing stop work orders to VA medical facilities for any time urgent circumstances that significantly impact health and safety of workers, public, or patients and recommending to Deputy Under Secretary for Health for Operations and Management (10N) stop work orders (in coordination with the national program directors above) for other circumstances that impact health and safety of workers, public, or patients.

f. Developing and issuing radiation protection program guidance for machine sources of ionizing radiation.

g. Veterans Integrated Service Network Director. The VISN Director is responsible for ensuring that fluoroscopy operations are in compliance with the requirements in this directive.

h. VA Medical Facility Director. If fluoroscopes are used at their medical facility, the VA Medical Facility Director is responsible for:

(1) Appointing an RSO in writing for machine sources at their medical facility to direct the radiation safety program and providing the name of the RSO to NHPP.

(2) Establishing a Radiation Safety Committee or other oversight committee as outlined in VHA Directive 1129.
(3) Ensuring that a fluoroscopy safety training program is established and that such training is required in order to operate a fluoroscope. This includes a credentialing process that includes validation from the RSO that fluoroscopy safety training has occurred prior to credentialing an individual.

(4) Ensuring all Supervising Fluoroscopic Operators meet the requirements of this directive through the credentialing and privileging process.

(5) Ensuring that personal dosimeters and radiation protective apparel are provided to persons operationally exposed to radiation in a work environment in accordance with 29 CFR 1910.1096.

(6) Ensuring that fluoroscopes are used in rooms with structural shielding that prevents radiation exposure from exceeding allowed limits to employees and the general public in adjacent spaces.

(7) Promoting a safety culture where employees feel free to report radiation safety incidents and deficiencies through the chain of command without fear of reprisal.

(8) Ensuring the medical facility implements a technical quality assurance program that conforms to the elements in Appendix D the American College of Radiology-American Association of Physicists in Medicine (ACR-AAPM) Technical Quality Assurance in Fluoroscopic Imaging (https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Fluoro-Equip.pdf) and the Joint Commission standards of ionizing radiation.

NOTE: This linked document is outside of VA control and may or may not be conformant with Section 508 of the Rehabilitation Act of 1973.

(9) Ensuring the facility is following the shielding as defined in Structural Shielding above.

(10) Ensuring the facility records doses to patients, reviews patient doses as part of the quality assurance program, performs patient follow-up, and reports of sentinel event and injuries as outlined in Appendix B and D.

(11) Reporting to NHPP radiation exposures to staff or members of the public that exceed regulatory limits.

   i. Radiation Safety Officer. The RSO, with respect to fluoroscopy, is responsible for:

   (1) Establishing and implementing radiation safety procedures commensurate with the use of fluoroscopy, and reviewing them periodically to ensure their conformity with Federal radiation safety regulations and this directive.

   (2) Ensuring regulatory standards for radiation safety and medical physics practices are followed throughout the facility (see references).
(3) Instructing personnel of requirements in Federal radiation safety regulations applicable to fluoroscopy and this directive, and proper radiation protection practices before first working with radiation; or making available a course of instruction for same.

(4) Conducting or supervising radiation surveys where indicated and to keep records of such surveys and tests, including summaries or corrective measures recommended or instituted.

(5) Ensuring that personal monitoring devices are issued as required by 29 CFR 1910.1096, that records are kept of the results of such monitoring, and that these monitoring reports are promptly reviewed to ensure that doses are ALARA and regulatory limits are not exceeded. **NOTE:** These records must be kept in a suitable organized file for the life of the facility. Spot checks that identify personal monitoring device discrepancies are reported to the individual’s supervisor for the appropriate remediation actions.

(6) Ensuring that required signs and notices are properly posted.

(7) Ensuring the chain of command is aware of safety problems that reporting requirements are followed as outlined in Appendix D.

(8) Ensuring prompt investigation of each known or suspected case of SRDL (as defined above) and determine the causes, take steps to prevent its recurrence, and monitoring such corrective actions.

(9) Ensuring that required notifications and reports in the case of overexposures of personnel and sentinel events are submitted to the Medical Facility Director. (See Appendix D Notifying the facility Director promptly of any significant safety hazards or other significant violations of this directive, and exposures of staff or members of the public that exceed regulatory requirements.

(10) Reviewing or having a qualified expert review, prior to construction, plans for rooms in which ionizing radiation producing equipment is to be installed, including room layout, shielding, viewing, and communications systems. Performing, or having a qualified expert perform, radiation surveys after installation but before clinical use of the equipment. **NOTE:** For any room in which a fluoroscopic imaging system is installed, or in which a mobile fluoroscopic imaging system is frequently used, the doses to persons in adjacent areas, including any areas above and below, must be evaluated by a medical physicist or medical health physicist.

(11) Keeping records of training, and of signed preceptor statements. **NOTE:** For information regarding records management, see VHA Directive 6300 for records control.

j. **Facility Service Chief.** The Service Chief, where fluoroscopy is utilized, is responsible for:

(1) Ensuring there are defined written protocols, describing the technique factors to be selected, for each model of fluoroscope that is used and for each category of
procedure to be performed on that fluoroscope. These may be in the form of a checklist used to ensure the proper selections at the beginning of each procedure.

(2) Ensuring that all personnel who work in the room where fluoroscopy is performed undergo radiation safety training. The training must be commensurate with risk to the staff. It must include the risks from exposure to ionizing radiation, requirements of this directive, facility requirements, and methods for maintaining doses to staff within established limits and ALARA, and for protecting the patient.

(3) Ensuring that appropriate staff performing or assisting with fluoroscopy wear dosimeters.

(4) Ensuring the service has written processes for the safe use of fluoroscopic equipment which includes the safety of the patient, operator and nearby staff and other personnel in close vicinity.

(5) Ensuring all radiation safety precautions are taken when personnel are using fluoroscopes for patients at the VHA medical facility, consistent with this directive and applicable Federal radiation safety standards and regulations.

(6) Ensuring appropriate safeguards for pregnant women. (See Appendix A 1b).

(7) Evaluating and certifying in conjunction with the RSO, whether the training received at the facility or elsewhere, meets the requirements defined in this directive by issuing a signed and dated memorandum stating the employee is qualified to operate fluoroscopes. However, this directive does not limit the ability of facility officers to prescribe additional training as deemed necessary.

(8) Recording the procedure to include dose metrics in a format such as a spreadsheet suitable for Quality Assurance (QA) review. (See Appendix D).

k. **Biomedical Engineering Service/Section.** The biomedical engineering service is responsible for: restoring the equipment back to the manufacturer’s specifications prior to first patient use after repairs or service have been performed. **NOTE:** Facilities must establish written processes within the 30 day time frame to perform testing by a biomedical engineer or a service engineer to validate dose output and image quality. **NOTE:** Facilities must establish written processes to perform testing by a biomedical engineer or a service engineer to validate dose output and image quality following repairs, and to obtain a Medical Physicist inspection within 30 days of the repair.

l. **Medical Physicist.** The medical physicist is responsible for performing initial and annual testing, and testing within 30 days after repairs or service on all X-ray producing equipment. After repairs or service, Biomedical Engineering is responsible for restoring the equipment back to the manufacturer’s specifications prior to first patient use. When a repair could change dose output or affect image quality, such as replacing an x-ray tube, generator, or image receptor, facilities must establish written processes to perform and document testing by Biomedical Engineering or a service engineer to validate dose output and image quality prior to its clinical use. A qualified medical...
physicist must perform verification testing as soon as reasonably feasible and within 30 days. Events that require medical physics testing will be reported and tracked in the Radiation Safety Committee meeting (or facility equivalent). **NOTE:** Acceptance testing performed by the VA National Acquisition Center (NAC) or a Biomedical Engineer does not eliminate the need for testing by a qualified medical physicist prior to first clinical use. The acceptance testing is solely to verify conformance with purchase.

m. **Supervising Fluoroscope Operator.** The Supervising Fluoroscopic Operator is responsible for:

1. Caring for the patient before, during, and after fluoroscopic procedures (see Appendix A) and for the effects from fluoroscopic exposures. The reporting requirements are detailed in Appendix B.

2. Making an announcement before the beam is turned on so that employees who are not wearing a lead apron may relocate to a safe distance, at a minimum of 10 feet from the fluoroscope (see Appendix E).

### 6. EQUIPMENT SPECIFICATIONS FOR FLUOROSCOPY EQUIPMENT

The fluoroscopic system used in VHA must conform to the performance specifications in 21 CFR Part 1020 that were in effect at the time of manufacture. The fluoroscopes must be equipped with a last image hold capability which displays the last image after the production of radiation ceases and fluoroscopic equipment manufactured on or after June 10, 2006, must display the cumulative air kerma at a reference point. Specifications for acquisition of new fluoroscopes need to include:

a. A display of the air kerma-area product in addition to the United States Food and Drug Administration (FDA) mandated cumulative air kerma delivered to a reference point. These are the standard measures of patient radiation exposure.

b. Support for Integrating the Health care Enterprise (IHE) Radiation Exposure Monitoring (REM) integration profile. This is the technical means by which exposure values are automatically stored in Veterans Health Information Systems and Technology Architecture (VistA) Imaging. **NOTE:** stored in VistA when software enhancement becomes available.

c. Each fluoroscopic system used in VA medical facilities must be maintained so that it conforms to the performance specifications in 21 CFR Part 1020 that were in effect at the time of manufacture.

d. Fluoroscopes that lack last image hold capability or that lack displays of cumulative air kerma at the reference point must not be used for potentially high radiation dose procedures.
7. TRAINING REQUIREMENTS

Initial radiation safety training is mandatory for all who operate or supervise the operation of a fluoroscope and must include the following:

a. Didactic training: this need not be performed at or by the VA medical facility, if and only if the trainee demonstrates:

   (1) Evidence of the date(s) of training;
   (2) The name(s) of the person(s) providing the training;
   (3) The topics included in the training;
   (4) The duration of the training;
   (5) The test questions, if available; and evidence of successful completion. **NOTE:** Individuals as identified in Appendix E, who have current fluoroscopy privileges in the VA at the effective date of this directive are deemed to have met the requirements of this section.

b. Physicians who have successfully completed a residency in an accredited Radiology residency program are considered to have met the didactic portion of the fluoroscopic training requirement.

c. Didactic training must include the following topics, with successful completion of a written examination:

   (1) Physics of x-ray production and interaction
   (2) The technology of fluoroscopy machines, including modes of operation
   (3) Characteristics of image quality and technical factors affecting image quality
   (4) Dosimetric quantities and units
   (5) Biological effects of radiation
   (6) Principles of radiation protection in fluoroscopy
   (7) Applicable Federal regulations and VHA requirements
   (8) Techniques for minimizing dose to the patient and staff

   **NOTE:** Technologists certified in radiology or radiation therapy from the American Registry of Radiologic Technologists (ARRT), or who are registered cardiovascular invasive specialists with Cardiovascular Credentialing International (CCI) are considered to have met the didactic portion of the training requirement.
d. Hands on Training: The facility must develop written processes that define hands-on training ideally needs to be conducted on the model of fluoroscope that is to be used. The training needs to encompass the use of controls, activation of various modes of operation, and displays. This phase of training may include: demonstrations of the effect of different modes of operation on the dose rate to a simulated patient, and may include demonstration of the dose-rates at various locations in the vicinity of the fluoroscope.

e. Preceptor Training: Preceptor training and certification consists of operation of the fluoroscope for clinical purposes under the personal supervision of a physician or a qualified fluoroscopy operator in the same clinical practice (i.e. A qualified physician assistant could precept another physician assistant) who is experienced in the operation of the device. Completion of this phase of training must include written confirmation, signed by the preceptor, that the individual has achieved a level of competency sufficient to function independently as a fluoroscopy operator.

f. Radiation safety training is required for all who work in the room where fluoroscopy is performed. Radiation safety training is performed initially and yearly thereafter. The training must be commensurate with risk to the staff. It must include the risks from exposure to ionizing radiation, requirements of this directive, facility requirements, methods for maintaining doses to staff within established limits and ALARA, and for protecting the patient.

8. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management you should contact your facility Records Manager or your Records Liaison.

9. REFERENCES

a. 10 CFR Part 20.

b. 21 CFR Part 1000, Subpart C.

c. 21 CFR Part 1020.

d. 21 CFR, Part 803.

e. 29 CFR 1910.1096.

f. 38 CFR Part 16.

g. 45 CFR Part 46.


l. VHA National Health Physics Program (NHPP), http://nhpp.med.va.gov/NHPP_Diagnostic_Radiology_Info.asp.

m. AAPM Report No. 58, Managing the Use of Fluoroscopy in Medical Institutions, 1998; https://www.aapm.org/pubs/reports/RPT_58.pdf. **NOTE:** This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.


o. ACR-AAPM Practice Parameter for Diagnostic Reference Levels and Achievable Doses in Medical X-Ray Imaging; https://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Reference_Levels_Diagnostic_Xray.pdf?la=en. **NOTE:** This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.


q. ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures; https://www.acr.org/~/media/F22C9D1FF46F43AAB001F9ED0466B7E9.pdf. **NOTE:** This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.

r. ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation; https://www.acr.org/~/media/9E2ED55531FC4B4FA53EF3B6D3B25DF8.pdf. **NOTE:** This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.

t. FDA, Avoidance of Serious X-Ray-Induced Skin Injuries to Patients during Fluoroscopically-Guided Procedures, September 9, 1994.

u. FDA, Recording Information in the Patient’s Medical Record that Identifies the Potential for Serious X-Ray-Induced Skin Injuries Following Fluoroscopically-Guided Procedures, September 15, 1995

v. ICRP Publication 84, Pregnancy and Medical Radiation, Pergamon, 2000; http://www.aawr.org/Portals/10/Members/ICRP%20Annals.pdf. NOTE: This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.


aa. NCRP Report No. 147, Structural Shielding Design for Medical X-Ray Imaging Facilities, 2004; https://www.ncrppublications.org/Reports/147. NOTE: This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.


dd. Additional Resources.

(1) American College of Cardiology Foundation (ACCF), American Heart Association (AHA), Heart Rhythm Society (HRS), and Society for Cardiac Angiography


PATIENT SAFETY ACTIONS BEFORE, DURING, AND AFTER FLUOROSCOPY

1. PATIENT PROTECTION BEFORE A FLUOROSCOPY PROCEDURE

   a. **Procedures to Ensure That the Correct Patient Receives the Intended Examination or Procedure.** Procedures requiring verification of the patient’s identity by at least two methods must be put in place. Precautions must be commensurate with the risk from the examination or procedure, with greater precautions being taken for procedures of greater risk.

   b. **Considerations for Pregnant Women.**

      (1) Signs must be posted in suitable locations, such as patient reception areas and procedure rooms, asking female patients to notify staff if they might be pregnant.

      (2) Precautionary procedures to determine whether a female patient of childbearing age may be pregnant must be mandatory and defined by local policy.

      (3) For procedures that are expected to deliver >50 mGY doses to a conceptus/fetus/embryo, a pregnancy test must be obtained within 72 hours prior to commencement of the procedure excluding medical emergencies. **NOTE:** A pregnancy test is not required if pregnancy can be ruled out by a prior hysterectomy or tubal ligation, postmenopausal state with absence of menstrual bleeding for 2 years, or by premenarche in a child.

      (4) If a patient is pregnant, a physician knowledgeable in the risk from the radiation exposure must counsel the patient on the risks of radiation and make a decision with the patient whether to proceed with the examination. Consideration must be given to alternate tests or procedures that would not expose the embryo or fetus to ionizing radiation; and to modifying the examination or procedure to reduce the radiation dose to the embryo or fetus.

   c. **Threshold for Radiation Injury.** Supervising fluoroscopic operators or Licensed Independent Practitioner (LIP) must determine, before each potentially high-dose procedure (SRDL), whether the patient has any condition that might significantly lower the threshold for radiation injury. These include:

      (1) Previous large radiation doses to the same part of the body from fluoroscopy procedures or radiation oncology treatments;

      (2) Certain rare hereditary diseases affecting deoxyribonucleic acid (DNA) repair, such as ataxia telangiectasia;

      (3) Hyperthyroidism and diabetes mellitus;

      (4) Certain autoimmune and connective tissue disorders;
(5) Certain drugs, including actinomycin D, bleomycin, doxorubicin, 5-fluorouracil, and methotrexate.

d. **Existing Skin Injuries.** Before each high dose procedure, the supervising fluoroscopic operator must view the patient's skin for evidence of skin injury from previous fluoroscopy or radiation oncology treatments. If there is evidence of such injury, operators must take precautions to avoid placing the x-ray beam on this area or these areas.

e. **Patient Consent.** The Supervising Fluoroscopic Operator is responsible for obtaining a signature consent from the patient for each potentially-high radiation dose procedure and the consent must mention the possibility of a tissue reaction of the skin. 

**NOTE:** See VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 24, 2009.

f. **Pre-Procedure Protocol.** Immediately before a procedure, an imaging protocol and settings appropriate for the clinical procedure must be selected on the fluoroscope based upon a written procedure or checklist.

2. **PATIENT PROTECTION DURING A FLUOROSCOPY PROCEDURE**

a. The x-ray tube must be kept as far from the patient as possible. When the x-ray tube is beneath the patient, this is done by raising the patient table as high as feasible, but not to the extent that it impedes the procedure. Do not remove the spacer device from a c-arm fluoroscope unless absolutely necessary, because that allows the x-ray source to be brought too close to the patient's skin. If a spacer must be removed, safety procedures must be implemented to verify that the x-ray source is acceptably far from the patient’s skin. Keep the image receptor as close to the patient as possible, except when deliberately using a gap for geometric magnification or scatter reduction.

b. Whenever possible, fluoroscopy operators must use x-ray beam angulations that minimize the path length of the x-ray beam through the patient’s body (e.g., posterior-anterior (PA) provides a shorter path length than lateral or cranio-caudal (CC) angulation of the beam) so that radiation dose to the patient and operator are minimized. In particular, when using lateral projections, ensure that the patient’s arms remain out of the beam.

c. Fluoroscopy operators must collimate the x-ray beam to the smallest area consistent with clinical needs.

d. Fluoroscopy operators must minimize the amount of time the beam is turned on. Fluoroscopy must be performed only to observe motion or to position the imaging system. Perform fluoroscopy intermittently with last image hold. Use the last image hold feature when there is a need to consider or discuss the image.

e. Fluoroscopy operators must limit the number of exposures recorded to the minimum that are clinically necessary.
f. When recording dynamic image sequences e.g., with Cinefluorography or digital subtraction angiography (DSA), fluoroscopy operators must use the lowest frame rate that is clinically acceptable. In cardiac catheterization laboratories, a cine frame rate of 15 images per second is commonly used for studies of the adult heart.

  g. When using pulsed fluoroscopy, fluoroscopy operators must select the lowest pulse rate that is clinically acceptable.

  h. In manual mode, fluoroscopy operators must use as large a setting of kilovolts (kV) as possible, consistent with adequate image contrast, and as small a setting of milliamps (mA), consistent with low-image noise.

  i. Fluoroscopy operators must minimize the use of magnification modes and high-dose-rate modes. When a magnification mode is needed, use the one with the least acceptable magnification.

  j. Remove the anti-scatter grid from the image receptor when removing it does not deteriorate the image quality, for example, in small sized patients and when the gap between the patient and the image receptor is large.

  k. Whenever possible fluoroscopy operators must avoid beam angles that place radiosensitive organs, such as the eyes and female breasts, in the x-ray beam on the x-ray source side.

  l. For long procedures, fluoroscopy operators must vary projection angles to avoid skin injuries.

  m. Fluoroscopy operators must be aware that dose to the patient’s skin and to staff accumulates much more rapidly in obese patients.

  n. Precautions must be taken to ensure that the patient’s arm is not in the x-ray beam during extreme lateral and oblique projections.

  o. A staff member must be assigned to notify the operator when the cumulative air kerma reaches 3 Gy and every Gy thereafter.

3. PATIENT PROTECTION AFTER A FLUOROSCOPY PROCEDURE

  a. A record must be made of the procedure to include dose metrics in a format such as a spreadsheet suitable for Quality Assurance (QA) review. **NOTE:** This temporary record for QA purposes should only be kept for tracking and trending and not as a part of RCS10-1. Each Service Chief or section reviews these records periodically, (e.g. monthly or quarterly) as part of its routine clinical QA program.

  b. Typical tissue reactions (deterministic effects) as a function of skin exposure can be found in Appendix B.
c. If the metrics of dose to the patient’s skin exceed a substantial radiation dose level, (as defined above), the physician performing the procedure or his/her designee must inform the patient of possible tissue reactions and actions to take if they occur, document the beam entrance skin locations and estimated doses to each in the patient’s medical record, arrange for patient follow-up appropriate to the estimated dose, and notify the RSO. **NOTE:** For each potentially-high radiation dose procedure, the deterministic risks of erythema and epilation must be discussed with the patient and documented in the medical record before the procedure begins.

d. Precautions must be taken to avoid biopsies of skin with radiation induced injury, because these may not heal, may serve as a portal for infection, and progress to a more severe wound.

e. After an interventional fluoroscopic procedure, there are a number of radiation skin effects of varying severity that may occur (discussed in detail in Appendix B), which the physician performing high-dose fluoroscopic procedures must communicate to the patient, including instructions for where to look for skin changes and how they appear.
POSSIBLE CLINICAL EFFECTS FROM FLUOROSCOPIC EXPOSURES AND REPORTING GUIDELINES

The following possible clinical effects may occur due to fluoroscopic exposures:

1. Skin doses of 2-5 Gy may cause a transient erythema or transient epilation within weeks. These will typically not need follow-up or medical intervention. They may, however, cause the patient to be concerned, if the patient has not been forewarned. For exposures between 3 and 4.9 Gy, a follow up appointment should be scheduled to look for potential skin issues.

2. Doses in the range of 5-10 Gy can cause itching, partial or permanent epilation and prolonged erythema and ultimately skin telangiectasia and atrophy. For exposures of over 4.9 Gy, the physician must verbally counsel the patient and/or care giver and it is recommended that patients with estimated peak skin doses of 5 Gy or more have documented follow-up examinations approximately 4 to 8 weeks post-procedure.

3. The most clinically significant long-term effect is ischemia with persistent ulceration and infection. Such injuries often will need full-thickness grafting. The absorbed dose that causes such effects is 15 Gy or more. These patients will demonstrate dry or moist peeling of the skin about 4-8 weeks after the procedure. Provisions must be made for follow-up and monitoring of patients who potentially may have clinically significant long-term radiation effects on the skin and subcutaneous tissues. An estimated peak skin dose must be calculated for procedures that have exceeded SRDL.

An article by Balter S. Hopewell et al in Fluoroscopy Guided Interventional Procedures: A Review of Radiation Effects on Patients’ Skin and Hair. Radiology 2010; 254: 326-341, identifies the typical deterministic effects of skin exposure to fluoroscopy and are followed in the VHA medical facilities:

a. For skin doses between 0 – 2 Gy no prompt, early, midterm, or late effects noted.

b. Skin dose between than 2 - 5 Gy, the immediate effect is transient erythema (within two weeks) followed by epilation within 2 – 8 weeks. Recovery from hair loss is noted between 6 – 52 weeks with no long term effects.

(1) If 3 Gy skin dose to single field is exceeded, estimated skin doses and locations must be recorded in the patient’s medical record by the supervising fluoroscopic operator. The patient must be instructed in self-examination of the skin for erythema and to report any radiation effects to the physician.

c. For skin doses between 5 – 10 Gy, transient erythema is noted within two weeks, followed by erythema epilation in 2 – 8 weeks. At lower doses there may be recovery between 6 – 52 weeks, but at higher doses prolonged erythema with permanent partial epilation is noted. There may be complete recovery, or at higher doses dermal atrophy or induration may be noted.
(1) If 5 Gy skin dose to a single field is exceeded, the RSO must be notified and arrangements must be made to have the patient examined by a health care practitioner approximately 4 to 8 weeks following the procedure, with subsequent examinations as appropriate.

d. For skin doses 10 – 15 Gy, transient erythema is noted early on (within 2 weeks), followed by erythema epilation or possible dry or moist desquamation and recovery from desquamation within 2 – 8 weeks. Midterm effects are seen as prolonged erythema and permanent epilation. Post 40 weeks telangiectasia, dermal atrophy or induration is observed. Skin is likely to be weak.

e. Any exposure that results in permanent skin damage is a Sentinel Event, and must be reported to the RSO and Patient Safety Manager when it is observed. However, permanent epilation to a part of the body other than the patient’s head, by itself, need not be considered a sentinel event. If 15 Gy (1500 rad) cumulative skin dose to a single field is exceeded, the incident must be reviewed as a sentinel event. The event must be reported to the RSO and to the Patient Safety Manager in accordance with VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011. The Joint Commission interprets cumulative dose as the sum of doses over a 6-month to 1-year period.

f. Any exposure that results in permanent skin damage (including permanent epilation of the head but excluding permanent epilation of the trunk and extremities), must be reported to the manufacturer of the fluoroscopic equipment and the FDA as required by 21 CFR 803. Additionally, any exposure resulting in skin injury that requires surgical repair must be reported to the VHA National Health Physics Program.

### TYPICAL TISSUE REACTIONS AS A FUNCTION OF SKIN EXPOSURE

<table>
<thead>
<tr>
<th>Skin Dose (GY)</th>
<th>Prompt Effect Less than (&lt;) 2 weeks</th>
<th>Early Effect 2 – 8 weeks</th>
<th>Midterm Effect 6 – 52 weeks</th>
<th>Late Effect More than (&gt;40 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 2</td>
<td>None Observed</td>
<td>None Observed</td>
<td>None Observed</td>
<td>None Observed</td>
</tr>
<tr>
<td>2 – 5</td>
<td>Transient erythema</td>
<td>Epilation</td>
<td>Recovery from hair loss</td>
<td>None observed</td>
</tr>
<tr>
<td>5 – 10</td>
<td>Transient erythema</td>
<td>Erythema, epilation</td>
<td>Recovery; at higher doses, prolonged erythema, permanent partial epilation.</td>
<td>Recovery; at higher doses, dermal atrophy or induration.</td>
</tr>
<tr>
<td>Skin Dose (GY)</td>
<td>Prompt Effect Less than (&lt;) 2 weeks</td>
<td>Early Effect 2 – 8 weeks</td>
<td>Midterm Effect 6 – 52 weeks</td>
<td>Late Effect More than (&gt; 40 weeks</td>
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<tr>
<td>10 – 15</td>
<td>Transient erythema</td>
<td>Erythema, epilation; possible dry or moist desquamation; recovery from desquamation.</td>
<td>Prolonged erythema; permanent epilation.</td>
<td>Telangiectasia; dermal atrophy or induration; skin likely to be weak.</td>
</tr>
<tr>
<td>&gt;15</td>
<td>Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required.</td>
<td>Erythema, epilation; moist desquamation.</td>
<td>Dermal atrophy; secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required; at higher doses, dermal necrosis, surgical intervention likely to be required.</td>
<td>Telangiectasia; dermal atrophy or induration; possible late skin breakdown; wound might be persistent and progress into a deeper lesion; surgical intervention likely to be required.</td>
</tr>
</tbody>
</table>
RADIATION DOSE STANDARDS, SAFETY AND PROTECTION

1. GENERAL RADIATION DOSE STANDARDS

Department of Veterans Affairs (VA) medical facility staff must use, to the extent practical, procedures and engineered controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA).

2. EXPOSURE STANDARDS FOR PREGNANT WOMEN, EMBRYOS, AND FETUSES OF THE HEALTH CARE EMPLOYEE

If an employee voluntarily declares her pregnancy in writing, the dose equivalent from occupational exposure to the embryo or fetus must not exceed 5 mSv (0.5 rem) during the entire pregnancy. This limit applies to the sum of the dose equivalents from radioactive materials and x-ray machine sources.

3. EXPOSURE STANDARDS FOR INDIVIDUALS NOT IN THE TREATMENT ROOM

The total effective dose equivalent to an individual member of the public may not exceed 1 mSv in a year, exclusive of natural background radiation and medical exposures to the individual. NOTE: The term “member of the public” includes employees who are not considered to be persons operationally exposed to radiation in a work environment. For example, the dose limit applies to a clerical employee whose office is adjacent to a room in which a fluoroscope is used.

4. EXPOSURE STANDARDS FOR MEDICAL PURPOSES.

Veterans and staff may only be exposed to the primary radiation beams of fluoroscopic imaging equipment for medical purposes, which includes exposure during research conducted in accordance with the Federal Policy for the Protection of Human Subjects (See 45 CFR Part 46 and 38 CFR Part 16). Individuals must not be exposed to primary radiation solely for training, to test equipment, or to obtain images for accreditation.

5. GENERAL SAFETY PROTECTION.

a. Fluoroscopy operators must maximize the distance from the point where the x-ray beam enters the patient, consistent with clinical duties. When the beam has a lateral angulation, if possible, the operator must stand on the image receptor side of the patient instead of on the x-ray tube side. Nurses must avoid sitting or standing near the patient unless they are making a patient assessment.

b. Medical facility staff must keep unshielded hands out of the primary beam. When manipulating devices in the beam such as biopsy needles, they must use forceps. If a hand must be in the beam, it must be there very briefly and on the side of the patient opposite the x-ray tube.
6. RADIATION PROTECTION APPAREL

a. **Lead (and non-lead) Aprons.** Lead (and non-lead) aprons are the most effective personal radiation protection means and must be worn by everyone in a fluoroscopy room (except the patient). Such apparel may reduce the dose received by over 90% (85%-99%) depending on the energy of the x-rays (kV setting) and the lead equivalent thickness of the apron. The thickness of a patient’s body part in the beam determines the kV that the machine uses. The fluoroscopy system will select a higher kV for an obese patient. Thus staff will be exposed to more scattered radiation with an obese patient. The same protective apparel apron will provide less protection when the beam is of higher energy (or higher kV). Apparel providing 0.5mm lead thickness equivalent is preferable. An apron/apparel with 0.35 mm lead thickness equivalence may be sufficient for most fluoroscopic procedures. For high workload, a wrap-around apron with 0.25 mm lead equivalence that overlaps on the front and provides 0.25+0.25=0.5 mm lead equivalence on the front and 0.25 mm on the back would be ideal. For low work load volume, a 0.25 mm lead equivalence apron may be sufficient. The RSO may authorize less protective apparel when the heavier apparel may cause or aggravate an injury; in this case, the effectiveness of the protection must be assessed by use of an under-the-apparel dosimeter. Staff in the room whose sides or backs may be exposed to scatter from the patient must wear aprons providing at least 0.25 mm lead equivalent on the sides and backs. When fluoroscopy is performed in a large room, such as an Intensive Care Unit (ICU), where it is not feasible for all personnel to wear radiation protective aprons, the operator must make an announcement before the beam is turned on so that employees may relocate to a safe distance, at a minimum of 10 feet from the fluoroscope or stand behind mobile lead barriers. **NOTE:** Portable lead shields, i.e. on wheels may be used as a temporary barrier.

b. **Glasses and Goggles.** Shielded glasses or goggles and gloves must be made available as needed. The operator must wear leaded glasses, goggles, or a full-face shield that provides radiation shielding. Protective eyewear provides shielding from scattered x-rays from the side and below, because the operator is usually looking at the display monitor while x-rays are generated.

c. **Ceiling-Mounted Radiation Shields.** Transparent ceiling-mounted radiation shields must be used whenever possible to minimize dose to the operator’s face. The shield is properly positioned when the operator can view through the shield the area on the patient where the x-ray beam traverses the patient.
1. REPORTING REQUIREMENTS

Each Department of Veterans Affairs (VA) medical facility conducting/using fluoroscopy imaging equipment must make notifications and reports regarding radiation exposures to staff or members of the public that exceed regulatory limits to the VHA National Health Physics Program (NHPP). See 10 CFR Part 20, 29 CFR 1910.1096, as applicable, for specific notification and reporting requirements.

Records of patient fluoroscopic procedures must be kept to record patient dose as identified in Appendix B. These records may be made manually or digitally. The dose information below must be assembled in a format (commonly captured in a spreadsheet) suitable for periodic medicine or radiology Quality Assurance (QA) review.

a. Manual Records of Dose. The record must list the fluoroscopy unit, date of the procedure, type of procedure, information identifying the patient, and the name of the physician operating or supervising the operation of the device. The record must also list the cumulative air kerma, kerma-area product, fluoroscopy time, and number of static images recorded. The record must be kept in the custody of the Chief of Service (COS) or designee. NOTE: Newer fluoroscopic systems display cumulative measures of skin dose, specifically cumulative air kerma and dose-area-product, as well as the cumulative fluoroscopy time, whereas older systems may display only the cumulative fluoroscopy time. The cumulative air kerma and dose-area-product include the contributions from both fluoroscopy and image recording.

b. Digital Records of Dose. Digital records may be made in several ways. The displayed dose page can be stored in VistA Imaging or in a Picture Archiving and Communication System (PACS). Dose can be stored either as an image of the dose page or as a Digital Imaging and Communications in Medicine (DICOM) Radiation Dose Structures Report (RDSR). It can be stored in a patient-identified dose registry if such a registry is available. Dose data from interventional cardiology procedures may be entered in the Clinical Assessment, Reporting, and Tracking System for Cardiac Catheterization Laboratories (CART-CL), as cumulative air kerma and/or dose area product.

c. Clinical Quality Assurance. Each service or section performing fluoroscopy must periodically (e.g., monthly or quarterly) review records of doses to patients as part of its clinical quality assurance program. Any reports of radiation-induced tissue reactions to patients must also be reviewed. Quality assurance must include all aspects of the imaging process:

(1) Image acquisition through image display,

(2) Monitoring the luminance and calibration of image acquisition display monitors used for fluoroscopy.
(3) The technical quality assurance program must include testing by a medical physicist of all fluoroscopy equipment. The equipment must be tested after installation and before first clinical use, and annually thereafter not to exceed 14 months.

2. DOSE CALCULATION

At the present time, there are no technical means to conveniently calculate the dose at the skin site that receives the highest exposure. The cumulative air kerma commonly under or overestimates peak skin dose, and is known to be a rough estimate. There are three predominant factors responsible for this inaccuracy:

a. **Backscatter.** The true skin dose may be a factor of up to 1.4 times the displayed reference point air kerma.

b. **Use of multiple x-ray beam angles.** This causes radiation to be distributed over multiple skin entry sites. When estimating dose, one may divide the exposure according to alternative projections taken. The possibility of overlap of two separate adjacent fluoroscopic fields, where skin dose of the overlapping area may receive the sum of the doses of the projections, must be taken into account.

c. **Reference dose calculations.** These are different than the exam that is performed because the skin of the patient is closer to or farther from the x-ray tube than the reference instance. Examples are an obese patient, or a cardiac catheterization patient with the x-ray tube on the right side, whose actual doses are higher than the displayed air kerma.

d. **Examples of dose calculations.** Skin deterministic effects are predicted by peak skin dose (see a. and b below). Peak skin dose is 1.4 times the actual cumulative AK of the most-exposed skin. New fluoroscopy equipment is expected to provide peak skin dose; older equipment does not and must be estimated as follows:

Three approaches may be used to approximate peak skin dose:

(1) First-Order approximation: Assume peak skin dose is reasonably represented by the displayed cumulative air kerma.

(2) Second-Order approximation: Estimate the percentage of beam-on time for the longest exposed projection, multiply by the displayed cumulative air kerma and then multiply by 1.4.

(3) Third-Order approximation: Estimate percentage of cumulative air kerma associated with longest exposed projection taking into account the different fluoroscopy modes used, correct for inverse-square exposure increase due to skin being closer to the tube than the reference distance, then multiply by 1.4.
The inverse-square equation for fixed-distance C-Arm is:

\[ AK_{\text{corrected}} = AK_{\text{initial}} \cdot (\text{IRP \ [cm]})^2 / (\text{skin to focal point distance \ [cm]})^2 \]

Ref: Interventional Reference Point (IRP) is 70 cm for the GE-9900

When unexpected skin effects occur, this third method is required to explain the effects. It is prudent for the physician to practice skin dose determination during routine cases and devise a method for estimating peak skin dose in real time.
QUALIFICATIONS OF FLUOROSCOPE OPERATORS

1. **Staff Physicians and Podiatrists.** In order to perform fluoroscopy or to directly supervise qualified non-physician personnel in the operation of a fluoroscope, a staff physician or podiatrist must have completed the training requirements detailed in (Training) and must also be specifically credentialed by the Executive Committee of the Medical Staff (ECMS) or similar committee for privileges in fluoroscopy.

2. **Resident Physicians.** A resident physician may operate a fluoroscope, or may personally supervise qualified non-physician personnel in the operation of a fluoroscope, provided that the resident physician has completed fluoroscopy safety training as defined by the residency program, has completed training on the equipment, and is supervised by an attending physician who is privileged in fluoroscopy and who checks each study as specified by the facility resident supervision policy. Personal supervision of the resident is required for all potentially-high radiation dose procedures. Other procedures can be performed under general supervision.

3. **Speech Pathologists for Video Esophagrams.** A speech pathologist may operate a fluoroscope (for video esophagrams only) under direct supervision of a radiologist or appropriately credentialed Licensed Independent Practitioner (LIP) after having completed the training requirements detailed in Section 7. Training Requirements.

4. **Nurse Practitioners.** A nurse practitioner can perform fluoroscopy for routine procedures if they have completed the training requirements detailed in Section 7. Training Requirements and are specifically credentialed by the ECMS. They may not perform potentially high radiation dose procedures.

5. **Physician Assistants (PAs).** PAs may perform fluoroscopy if the ECMS has approved the expanded scope of practice in this area as required by VHA Directive 1063 and the physician assistant has completed the training requirements detailed in Section 7. Training Requirements. Routine procedures fall under the guidance for direct supervision. High risk interventional procedures or potentially-high radiation dose procedures fall under the guidance for personal supervision.

6. **Diagnostic Radiologic Technicians (DRTs).** A DRT, General Schedule (GS) 647, may operate a fluoroscope under the personal supervision of a fluoroscopy-trained physician or LIP. The only exceptions are for positioning or localizing procedures for which the technologist must be under the direct supervision of fluoroscopy-trained physician or LIP. For video esophagrams with a qualified Speech Pathologist, the DRT may position the fluoroscope and the Speech Pathologist must deliver the ionizing radiation during the exam (i.e. step on the pedal).

7. **Qualifications for Catheterization Medical Instrument Technician (CCMIT).** A CCMIT, GS-649, may operate a fluoroscope during a cardiology procedure only under the personal supervision of a fluoroscopy-trained cardiologist, provided they have completed the training requirements detailed in Section 7. Training Requirements.
8. **Qualifications for Registered Nurses (RNs).** RNs may operate fluoroscopes provided they have completed the training requirements detailed in Section 7. Training Requirements, if the procedure is within their area of competency, and under the personal supervision of an LIP trained in fluoroscopy. Examples include, but are not limited to:

   (a) A nurse in the operating room who positions and collimates a portable fluoroscope during a surgical procedure under the direction of a fluoroscopy-trained surgeon.

   (b) A nurse assigned to the gastrointestinal medicine service that centers a fluoroscope and turns on the beam under the direction of a fluoroscopy trained gastroenterologist.

9. **Qualifications for Diagnostic Medical Physicists (DMP) and Medical Health Physicists (MHP).** A DMP or MHP is qualified to perform quality assurance testing of all fluoroscopes and does not need to be supervised for fluoroscope testing.
Radiation Protection During Pediatric Fluoroscopy
Introduction

As a member of the imaging team, it is of utmost importance that technologists are dedicated
to decreasing the radiation dose, especially for pediatric patients. An important tool in
diagnosing medical conditions is fluoroscopy. Other diagnostic tools such as ultrasound and
MRI provide valuable information without the risk of radiation, but the use of fluoroscopy in
certain diagnostic exams cannot be avoided.

As Low as Reasonably Achievable (ALARA) is a recommendation from The International
Commission on Radiologic Protection and should be the guide for imaging professionals.
Achieving a diagnostic image while using the lowest possible dose is the goal of every
technologist.

Why is radiation safety in fluoroscopic imaging of
special concern for pediatric patients?

- Some organs in children are more
  radiosensitive than those in adults.

- Have a longer expected lifetime for the effects from
  radiation exposure to potentially develop into
cancer.

- Receive a larger radiation dose than is necessary to
  produce a useful image when the fluoroscope uses x-
ray equipment settings designed exclusively for adults.
Why is radiation protection of higher concern during pediatric fluoroscopy exams?

- Children are more radiosensitive than adults for about 30% of cancers (e.g., leukemia, thyroid, skin and brain). The younger the child, the more sensitive his or her body is; an infant is even more sensitive than a teenager to the effects of radiation for the same dose.

- Children have a longer expected lifetime for the effects from radiation exposure to potentially develop into cancer. The fact that children will likely live longer after an imaging study that uses ionizing radiation increases their risk in comparison to adults. For example, the cancers that developed in Japanese children after the atomic bomb took over 40 years to occur.

- Children receive a larger radiation dose than is necessary to produce a useful image when the fluoroscope uses x-ray equipment settings designed for adults.

Radiation Effect

The primary biologic effect of ionizing radiation is damage to a cell's DNA. Eric Hall, a highly regarded health physicist states, "These biologic effects include cell killing, carcinogenesis and mutations." As x-rays pass through the patient’s body, they interact with tissue molecules. The kinetic energy given to electrons by these interactions causes the electrons to move. The negative charge of the electron ionizes other molecules in its path. The ion track that is created may or may not result in DNA changes in the nucleus of the cell. In the vast majority of interactions between radiation and cells, the cell suffers no harm. When damage to DNA occurs, most of it is repaired within 24 hours.
What Are Tissue Effects?

- As radiation dose increases, the severity of injury increases
- Examples of injury:
  - Skin erythema (redness) and ulceration
  - Hair loss
  - Cataracts

Tissue effects occur when a large number of cells are damaged so severely that the either die immediately or are unable to reproduce. Multiple cells in the human body must be affected to result in a tissue effect. As the radiation dose increases, the severity of the injury increases.

Except for the lens of the eye, there are relatively fixed values of radiation dose above which tissue effect occur. The time it takes for tissue effects to occur is variable, but they tend to occur in days or weeks to months, and occasionally, even years after the radiation event.

Tissue effects are unlikely to occur at radiation doses from routine diagnostic exams such as an upper GI exam. However, tissue effects can occur during complex interventional procedures where the fluoroscopic radiation dose is elevated. Also, multiple radiation doses separated by time (multiple days to years) have a cumulative effect that result in tissue effects.

What Are Stochastic Effects?

- Damage that occurs in a single cell
- Results may appear years later
- Severity is not proportional to the radiation dose
- The likelihood of injury is proportional to radiation dose

A stochastic effect, or injury, represents random damage that occurs to a single cell. Radiation-induced cancers are stochastic effects. The cell is able to reproduce, but due to DNA damage, mutations may be carried into subsequent generations of cells. This may result in cancer years later. Because of the random nature of the injury, a threshold dose does not exist for stochastic injury. Although the severity of the injury is not proportional to the radiation dose the likelihood of an injury does appear to be proportional to the radiation dose.
The risk of stochastic effects is greater in children than adults because a child typically has a longer lifetime after irradiation in which the stochastic effect can be expressed. One cannot be certain that cancers are a direct result of the radiation doses received from medical imaging.

**Does Ionizing radiation used in Medical Imaging Cause Cancer?**

There is much debate in the imaging community about whether levels of radiation used in diagnostic medical imaging cause cancer. Studies of large groups suggest that the lifetime risk of cancer incidence is higher for those who were exposed to radiation as children. However, the potential for cancer is one individual is a chance occurrence. The chance of radiation-induced cancer is similar to your chances of winning the lottery, it is extremely unlikely that you will. If you purchase two lottery tickets, the chance of winning with each ticker is identical. However, the likelihood of winning does appear to be proportional to how many tickets you buy.

In the United States, cancer affects 40% of the population. Currently, it is impossible to determine with certainty whether a patient’s cancer is a result of his or her own biology, environmental effects, including natural sources of radiation, or as the result of a clinical procedure involving x-ray.

**Communicate Radiation Concerns**

- It is best if families receive information describing their child’s imaging study before the day of the examination

The physician who requests the examination or the hospital or facility personnel should provide this information at the time of scheduling. Providing parents with a simple brochure before the procedure has been shown to improve understanding. Parents’ questions should be answered simply and directly. The radiologic technologist can inform parents that the study is being performed to provide specific answers to their doctor’s questions. The radiologic technologist can describe the examination in simple terms and reassure the parents that the medical imaging team will “child size” the radiation dose and do everything possible to make the procedure as brief and painless as possible. Typically, parents are grateful for the information and the opportunity to have their questions answered.
Who are members of the Imaging Team?

- Radiologist
- Radiologic Technologist
- Medical Physicist
- Equipment Manufacturer

The imaging team members must understand the design and configuration of the fluoroscope’s controls well enough to properly manage the radiation dose to the patient while maintaining diagnostic image quality. That is, all team members must know how to adjust dose settings, collimation, pulse rates and widths, voltage and filter selection. Technique factors must be selected that provide only the necessary dose for the clinical task at hand.

Role of the Radiologist

The radiologist or other physician who uses medical imaging must ensure the procedure is appropriate and consider alternative lower dose options such as ultrasound or MRI in consultation with the referring physician. During the fluoroscopic procedure, the imaging physician must ensure that the lowest dose settings and the shortest amount of fluoroscopic time are used while providing the necessary diagnostic information.

The Imaging physician is responsible for:

- Directing the imaging team
- Ensures dose is as low as reasonably achievable
Role of the Radiologic Technologist

The radiologic technologist’s role is ensuring that the patient is properly prepared for the procedural part of the examination as well as addressing the patient’s emotional stress.

The radiologic technologist is responsible for:

- Prepare patient for examination
- Explain exam and answer questions
- Ensure all supplies and contrast material is available
- Ensure protective aprons and gonad shields are available and utilized
- Select appropriate equipment settings (ALARA)
- Acquire images
- Archive images

Role of the Medical Physicist

The medical physicist is a practicing medical imaging physicist certified by the American Board of Radiology, American Board of Medical Physics, or Canadian College of Physicists in Medicine in the field of diagnostic medical physicist. The physicist should work with the manufacturer of the fluoroscope during the installation of the unit to ensure that the fluoroscope is properly configured for children. Prior to first clinic use, the physicist should complete acceptance testing of the fluoroscope to verify the correct operation of all features likely to be used clinically. In addition, the physicist periodically monitors the equipment over its lifetime for quality improvement purposes. The individual should also work with the medical imaging team to clarify dose saving steps that can be taken during fluoroscopic procedures.

The medical physicist is responsible for:

- Evaluate equipment is functioning properly and meets requirements
- Ensure proper utilization of radiation film badges
- Ensure protective aprons and shield are routinely checked for defects
Role of the Equipment Manufacturer Service Provider

The manufacturer has two primary roles. First, the manufacturer should provide fluoroscopic equipment that is “optimized” to image children. This means that the equipment is designed to operate at the low dose setting while providing diagnostic image quality for the clinical task. Fluoroscopic units are primarily configured for adults and must be modified, particularly for small children through consultation between the physicist and the manufacturer’s representatives. Second, the manufacturer has a role in providing adequate instruction and training on the safe operation of the device for different-sized patients.

- Perform routine preventive maintenance to ensure proper calibration and performance
- Provide equipment in service training

What is fluoroscopy?

- Creates a sequence of images for the purpose of observing real-time motion in the human body
- In pediatric fluoroscopy, an additional goal is to balance image quality with the radiation dose

Fluoroscopy is an imaging method that uses x-rays to create a sequence of images for the purpose of observing real-time motion in the human body. This technique is most useful in evaluating organs and blood vessels and for guiding both diagnostic and interventional examinations. Fluoroscopy demonstrates motion by creating a series of images at a rate of 30 images per second. In pediatric fluoroscopy, an additional goal is to balance image quality with radiation dose necessary to produce clinically useful image.
Major Components of a Fluoroscope

- X-ray tube – source of the x-rays
- Generator – produces and controls the energy supplied to the x-ray tube
- Table – used for patient positioning
- Grid – removes scatter radiation
- Image Receptor – a flat panel detector or image intensifier
- Display Devices – display the created images

How Are X-rays Produced?

- Changes in the tube current changes the number of x-rays produced
- Changes in voltage applied to the tube change the energy carried by each x-ray

X-rays are created when a high-energy electron beam is stopped by a collision with the anode of the x-ray tube converting a portion of the electron beam’s energy carried by the x-ray photons. Changing the tube current or the tube voltage alters the energy of the x-ray beam. Increasing the tube current increases the number of x-rays, while increasing the voltage applied to the x-ray tube primarily increases the energy by each x-ray.

Fluoroscopy Equipment

- Typically, the equipment has the x-ray tube mounted under the table inside a tube assembly to hide the hardware
- The image receptor is mounted above the table
- The tabletop, the x-ray tube and the image receptor can be tilted as a single unit

Fluoroscopic equipment used for general diagnostic purposes typically has the x-ray tube mounted under the table inside a tube assembly. The image receptor is mounted above the table. Both the x-ray tube and the receptor are aligned and move as a single unit. The tabletop on which the patient rests can be moved side-to-side or toward the head or the feet of the patient. The tub, which encloses the x-ray tube, tabletop and image receptor, can be tilted as a single unit. If the room also has an overhead x-ray tube, the diagnostic fluoroscopy machine will contain a digital radiography detector or a Bucky tray for a film-screen cassette or a computed radiography cassette.
C-arm Fluoroscope

The mobile C-arm fluoroscope is designed to be used in multiple locations, such as operating rooms in a surgery suite. As indicated by its name, the main component of the unit is a rigid metal “C-shaped” arm with the x-ray tube and image receptor mounted on opposite ends. The C-arm can be rotated, raised and lowered, or swiveled to better evaluate the body part of interest.

Interventional Fluoroscopy Equipment

- Designed to better manage dose delivered to the pediatric patient
- Provides one or two planes of imaging on the same patient
- Biplane configurations are common in pediatric interventional fluoroscopic rooms due to the limited amount of iodine contrast material that can be tolerated by a small child

Fluoroscopic equipment used for angiography or other complex interventional procedures is designed to provide precise control of x-ray production with special features, many of which are designed to better manage the dose delivered to the pediatric patient. While these units also use the “C-shaped” arms, they are permanently installed within the room. The design permits positioning the C-arm with greater flexibility, control and speed. These units are designed to provide one or two planes of imaging on the same patient. Biplane configurations are common in pediatric interventional fluoroscopic procedure rooms due to the limited amount of iodine contrast material that a small child can tolerate.

Image Receptors

There are two types of image receptors that absorb the x-rays that exit the patient’s body and convert to the clinical image. The image intensifier converts the energy of the x-ray beam to a visible light image, which is coupled and focused on the lens of the high-definition TV camera, which digitizes the image. A newer technology, the flat-panel detector converts the energy of the x-ray beam to a digital format without the need for a TV camera. Both types of image receptors create a digital image that is processed to improve the image quality prior to display.
What is Radiation Dose?

- Radiology dose is the amount of radiation absorbed by a patient
- The unit of radiation dose is the gray (Gy)
- Methods to quantify dose:
  - Air Kerma
  - Kerma area product
  - Absorbed dose
  - Equivalent dose
  - Effective dose
  - Background radiation dose
  - Cumulative dose
  - Peak dose

The radiation dose is the amount of radiation energy absorbed by a patient. The unit of radiation dose is the gray (Gy). There are numerous methods to quantifying dose. The quantification method depends on which aspect of the topic one chooses to communicate; air kerma, kerma area product, absorbed dose, equivalent dose, effective dose, background radiation dose, cumulative dose or peak dose.

Factors Affecting Radiation Dose

- The design and configuration of the fluoroscopic machine
- Fluoroscopic machine operation by the fluoroscopist

There are two fundamental factors, excluding patient size that affect the patient’s total radiation dose and require careful management. They are (1) the design and configuration of the fluoroscopic machine and (2) its operation by the fluoroscopist. Machine design and configuration determine the patient’s radiation dose rate during fluoroscopy and the radiation dose used to create each recorded image. The operation of the machine, specifically taking advantage of the design features of the fluoroscope, has a significant effect on the number of fluoroscopic and recorded images that are created during the examination. The product of the number patient for each image determines the total radiation dose delivered to the patient.
What is Air Kerma?

- Kerma stands for kinetic energy released in a mass
- The unit of measurement is gray or milligray
- Specifies the intensity of the x-rays at the given position in space (air) at a known distance from the source of the x-rays
- Air kerma replaces the former quantity of “exposure”

When medical physicist performs dosimetry measurements on an x-ray or fluoroscopic unit, they are typically measuring air kerma. Air kerma, along with related patient factors, can be used to perform dose calculations.

What is Air Kerma Product?

Kerma-area product (KAP) is the mathematical product of air kerma and the cross-sectional area of the x-ray beam at the same location in space. Unlike area kerma, KAP is not affected by the distance from the focal spot. The intensity of the beam decreases at the same rate with distance, as the area of the x-ray beam increases.

Absorbed Dose

- Absorbed dose is the energy imparted per unit mass by ionizing radiation to matter at a specific point
- The unit of measure for absorbed dose is again the gray or milligray

Absorbed dose is often used interchangeably with the term radiation dose. This is the most basic and common type of dose discussed.

Equivalent Dose

- Equivalent dose is an absorbed dose multiplied by a quality factor

Equivalent dose is the absorbed dose value multiplied by a quality factor, which is determined by the type of particles or rays that carry the radiation energy through space. Occupational dose reports, generated from measurements by the radiation monitors worn by
technologists and fluoroscopic operators, are reported as equivalent dose. Because the quality factor for x-rays is 1, equivalent dose and absorbed dose are equal for x-rays. For this reason absorbed doses of x-ray, other than in occupational dose reports, are typically not expressed as equivalent dose. The unit of measure for equivalent dose is the sievert (Sv) or mSv.

**Background Radiation Dose**

- Background radiation is the radiation that comes from the environment around us
  - Sun
  - Earth’s crust
  - Food we eat
- Background radiation results in the whole body absorbed dose of approximately 3 mSv annually

Background radiation is radiation that comes from our environment. The sun continually emits high-energy x-rays, called cosmic rays, and trace amounts of naturally occurring radioisotopes with long half-lives are found in the earth’s crust. Human beings are dependent upon food sources rooted in the earth’s crust, so much of the food that we eat is slightly radioactive. All this radioactivity results in the whole-body absorbed dose of approximately 3 mSv annually. Radiation doses from fluoroscopic examinations are commonly compared to background radiation doses to provide patients or their caretakers with a frame of reference with respect to the risk.

**Entrance Skin Dose**

- Entrance skin dose (ESD) is the amount of radiation dose absorbed by the skin where the x-ray beam enters the patient
- The skin dose is highest where the beam enters the patient, typically on the back
Cumulative Skin Dose

- The cumulative skin dose is the absorbed dose where the beam enters the patient’s skin over the length of the procedure.
- The cumulative skin dose overestimates the possibility of tissue effects unless only one skin port is used.
- Many fluoroscopes today display the total amount of radiation produced, air kerma.
- From total air kerma, a medical physicist can calculate an estimate of the total skin dose.

The cumulative skin dose is the absorbed dose where the beam enters the patient’s skin summed over the duration of the procedure. The cumulative skin dose assumes that all radiation enters the body through one skin “window” or port. Since the x-ray beam is typically moved to different areas during a procedure, it is unlikely that any single area of skin would receive a radiation dose as high as the cumulative skin dose. However, the cumulative skin dose is important for determining the potential for skin injury or other tissue effects that result from high skin doses delivered during the procedure.

Today, many fluoroscopes display an indication of total air kerma, the total amount of radiation production, at a known distance from the source. From this total air kerma, a medical physicist can calculate an estimate of skin dose during the procedure.

Peak Skin Dose

- The peak skin dose is the maximum dose that any patch of skin of the patient receives during a clinical procedure.
- Peak skin dose is typically significantly less than the cumulative dose.
- Peak skin dose helps predict the likelihood of tissue effects.

The peak skin dose is the maximum dose that any patch of the patient’s skin receives during a clinical procedure. Since multiple skin ports are typically used either from moving the patient or repositioning the x-ray tube, the peak skin dose is typically significantly less than the cumulative skin dose. The size of the reduction factor between the peak skin dose and cumulative dose is a function of how many skin ports were used and if any of the skin port...
areas overlapped with one another. The peak skin dose is important for determining the likelihood of tissue effects.

**Variation in Pediatric Size**

- Variation of size in pediatric patients ranging from the smallest premature infant weighing less than two pounds to the 250-pound teenager
- As x-rays penetrate patients of different sizes, the concept of half value layer (HVL) is important to understand

Some think pediatric hospitals only specialize in the health care needs of infants and small children, but some adolescents are “adult-sized.” Tiny neonates can have a body thickness of less than 6 cm at their abdomen while the largest teenager abdomens can exceed 35 to 45 cm for anterior-posterior and lateral dimensions respectively. The majority of pediatric patients fall somewhere between these two extremes. This difference in tissue thickness has significant implications for both the equipment and the operator during pediatric fluoroscopy.

**Half Value Layer**

- Half value layer (HVL) is the amount of tissue that will reduce the quantity of x-rays to half the original number
- At 70 kV an increase in patient thickness by 3 cm doubles the number of x-rays required to penetrate the patient

Half-value layer (HVL) is the amount of tissue that will reduce the quantity of x-rays to half their original number. Because the HVL of soft tissue at 70 kV is approximately 3 cm, an increase in patient thickness by 3 cm doubles the number of x-rays required to penetrate the patient provided the kV and added filtration in the x-ray beam remain unchanged. A difference of more than 10 HVLs between the smallest and largest pediatric patient requires a dynamic range of 1,000 times the number of photons. Fluoroscopic equipment must be capable of providing acceptable images over the very broad range of patient sizes. The required high rate of x-ray output (air kerma rate) to image the largest adult patients drives many of the design features of fluoroscopes. The challenge remains to provide fluoroscopic configurations that reduce and properly manage the radiation dose rate for the smallest patients.
Air Kerma Rates Between Adult and Pediatric Patients

- Fewer x-rays are needed to image children compared to adults
- This provides opportunities to improve image quality and reduce the radiation dose to small children
- Equipment should be configured to deliver the quantity of x-rays required by the patient’s unique size

In clinical practice of pediatric imaging, the number of x-rays required is significantly reduced compared to those required for imaging adults. Therefore, there are opportunities to improve image quality and better manage patient dose for children and infants. Achieving this requires appropriate configuration changes to the fluoroscope, which delivers the quantity of x-rays as determined by the patient’s size. For example, to image the largest teenage patients, the radiation output rate required during fluoroscopy can be 90 mGy/min or more. In contrast, a properly configured fluoroscope for a newborn delivers 1 to 2 mGy/min or less.

Maintaining Image Quality

- Lower air kerma rates are sufficient to penetrate the small body of a child
- Goal is the correct dose to the image receptor with a reduced dose to the patient
- Managing dose to the image receptor manages overall quality of the diagnostic image

Reducing radiation dose and maintaining image quality is difficult with large patients because of the higher air kerma rates needed to penetrate the patient. Lower air kerma rates are sufficient to penetrate the smaller pediatric body. This requires numerous changes to the control features of the fluoroscope. The goal is to deliver the required number of x-rays at the image receptor to maintain diagnostic image quality while reducing patient dose, particularly to the patient’s skin. Maintaining appropriate air kerma rates at the image receptor avoids increases in noise in the image and maintains diagnostic image quality.
How Does X-ray Tube Voltage Affect Pediatric Patient Dose?

Subject contrast refers to changes in brightness of adjacent areas in the image and is due to the difference in transmitted x-ray intensity in one area of the patient compared to adjacent areas. It results from differences in the attenuation of the x-ray beam as it passes through different tissues in the patient. For example, bone \((z = 13.8)\) compared to soft tissue \((z = 7.4)\) transmits fewer x-rays and is more easily viewed in the image. Subject contrast depends on the:

- Difference in thickness of the body part imaged (e.g. neck vs. abdomen)
- Density difference between two body parts (e.g. air-containing lung vs. abdomen)
- Differences in atomic number (e.g., bone vs. soft tissue)
- Quality of the x-ray beam \((kV)\)

Subject Contrast Different in Pediatric vs. Adult Imaging

Subject contrast is different in children when compared to adults because of several factors. Subject contrast in the clinical image is determined primarily by the difference in the atomic number between two adjacent tissues. Since the atomic number of soft tissues varies little from its average value of 7.4, subject contrast of soft tissues is limited without the use of an external contrast agent. The subject contrast between bone and soft tissue in adult imaging is significant because the bone is fully calcified with an atomic number of approximately 14. However, subject contrast between bone and soft tissue in the pediatric image is comparatively less because the incomplete calcification of the pediatric skeleton, a factor that changes with age.

Subject contrast diminishes as the energy of the x-rays increases, which occurs when the voltage \((kV)\) used to produce the x-rays increases. This loss can be partially recovered by magnifying the subtle differences in subject contrast with digital image processing. Lower \(kV\) values can improve subject contrast but increase patient dose. The desire for more contrast must be balanced against the increase in patient dose. Fortunately, the increase in patient dose is not as large in the small child compared to the adult patient if small decreases in voltage are selected.
What Role Does Sharpness Play in Pediatric Imaging?

A sharp image is essential in pediatric imaging to visualize small anatomical structures. For example, the size of a patient’s heart is approximately the size of the patient’s fist. For pediatric patients’ areas of interest, obtaining the sharpest image possible is extremely important.

A smaller focal spot improves the geometric sharpness in the image and can be selected for small patients because higher air kerma rates necessary for adults are not required during pediatric imaging.

What Role Does Quantum Mottle Play in Pediatric Imaging?

Quantum mottle is a form of noise that occurs when there is an inadequate air kerma rate (number of x-rays) arriving at the image receptor. As a result, the image will be grainy or speckled in appearance. An increase in quantum mottle in the image reduces low contrast resolution, or the ability to distinguish a single object with a contrast level slightly different than its background. Increasing the air kerma rate at the image receptor reduces quantum mottle. Therefore, the need for good, low contrast resolution in the image must be continually balanced against the required increase in radiation dose to the image receptor, which increases the radiation dose to the pediatric patient.