

## 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 physicians' inspection of x-ray equipment following repair services or modifications.
- f. Training requirements for fluoroscopic procedures.

**3. RELATED ISSUES:** VHA Handbook 1050. 01, VHA National Patient Safety Improvement Handbook; VHA Directive 1063, Utilization of Physicians Assistants (PAs); and VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation.

**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.

**5. RESCISSION:** VHA Handbook 1105.04, Fluoroscopy Safety, dated July 6, 2012.

**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 This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**DATE**

**VHA DIRECTIVE 1105.04**

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Executive in Charge

***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. It

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.”

l. **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 cm<sup>2</sup>.

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 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.

- h. VHA Directive 1004.01, Informed Consent for Clinical Treatments and Procedures, dated September 20, 2017.
- i. VHA Directive 1063, Utilization of Physicians Assistants (PA), dated December 24, 2013.
- j. VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.
- k. VHA Handbook 1050. 01, VHA National Patient Safety Improvement Handbook, dated, March 4, 2011.
- l. VHA National Health Physics Program (NHPP), [http://nhpp.med.va.gov/NHPP\\_Diagnostic\\_Radiology\\_Info.asp](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](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.*
- n. AAPM Report No. 74, Quality Control in Diagnostic Radiology (Task Group 12), 2002; <http://www.aapm.org/pubs/reports/detail.asp?docid=73>.
- 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](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.*
- p. ACR-AAPM Technical Standard for the Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment; [https://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Fluoroscopic\\_Equipment.pdf](https://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Fluoroscopic_Equipment.pdf). **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.*

- s. EPA's Federal Guidance Report No. 14, <https://www.epa.gov/radiation/federal-guidance-report-no-14-radiation-protection-guidance-diagnostic-and-interventional>
- 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.*
- w. ICRP Publication 85, Avoidance of Radiation Injuries from Medical Interventional Procedures, Pergamon, 2000.
- x. ICRP Statement on Tissue Reactions, April 21, 2011; <http://www.icrp.org/docs/2011%20Seoul.pdf>. **NOTE:** *This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*
- y. NCRP Report No. 99, Quality Assurance for Diagnostic Imaging, 1988; <http://ncrponline.org/publications/reports/ncrp-report-99/> . **NOTE:** *This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*
- z. NCRP Report No. 102, Medical X-Ray, Electron Beam, And Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance, and Use), 1989; <https://www.ncrppublications.org/Reports/102> .
- 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.*
- bb. NCRP Report No. 168, Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures, 2010; <https://www.ncrppublications.org/Reports/168>. **NOTE:** *This linked is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*
- cc. International Commission on Radiation Units and Measurements, <http://www.icru.org/>
- dd. **Additional Resources.**
  - (1) American College of Cardiology Foundation (ACCF), American Heart Association (AHA), Heart Rhythm Society (HRS), and Society for Cardiac Angiography

and Interventions (SCAI) Clinical Competence Statement on Physician Knowledge to Optimize Patient Safety and Image Quality in Fluoroscopically Guided Invasive Cardiovascular Procedures, *Journal of the American College of Cardiology (JACC)*, 2004, 2259-2282.

(2) Balter S, Hopewell JW, Miller DL, et al. Fluoroscopically Guided Interventional Procedures: A Review of Radiation Effects on Patients' Skin and Hair. *Radiology* 2010; 254: 326-341.

(3) Cardiovascular Credentialing International, <http://www.cci-online.org/>.

(4) International Commission on Radiation Units and Measurements, <http://www.icru.org/>.

(5) Koenig TR, Wolff D, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures, part I: characteristics of radiation injury. *American Journal of Roentgenology (AJR)* 2001;177:3-11.

(6) Koenig TR, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: part II, review of 73 cases and recommendations for minimizing dose delivered to patient. *AJR* 2001;177:13-20.

(7) Stecker MS, Balter S, Towbin RB, et al. Guidelines for Patient Radiation Dose Management. *Journal of Vascular and Interventional Radiology* 2009; 20:S263–S273.

(8) Image Wisely® , Fluoroscopy <https://www.imagewisely.org/Imaging-Modalities/Fluoroscopy>.

(9) Fluoroscopy Protocols. Priscilla F. Butler, MS, FACR, FAAPM *American College of Radiology, Reston, VA*; Published November 25, 2014 <https://www.imagewisely.org/imaging-modalities/fluoroscopy/articles/butler-fluoroscopy-protocols>.

**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**

<b>Skin Dose (GY)</b>	<b>Prompt Effect Less than (&lt;) 2 weeks</b>	<b>Early Effect 2 – 8 weeks</b>	<b>Midterm Effect 6 – 52 weeks</b>	<b>Late Effect More than (&gt;) 40 weeks</b>
0 - 2	None Observed	None Observed	None Observed	None Observed
2 – 5	Transient erythema	Epilation	Recovery from hair loss	None observed
5 – 10	Transient erythema	Erythema, epilation	Recovery; at higher doses, prolonged erythema, permanent partial epilation.	Recovery; at higher doses, dermal atrophy or induration.

Skin Dose (GY)	Prompt Effect Less than (<) 2 weeks	Early Effect 2 – 8 weeks	Midterm Effect 6 – 52 weeks	Late Effect More than (>) 40 weeks
10 – 15	Transient erythema	Erythema, epilation; possible dry or moist desquamation; recovery from desquamation.	Prolonged erythema; permanent epilation.	Telangiectasia; dermal atrophy or induration; skin likely to be weak.
>15	Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required.	Erythema, epilation; moist desquamation.	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.	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.

## 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.

**REPORTING REQUIREMENTS OF DOSE AMOUNTS****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 2. 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:

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

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