

FLUOROSCOPY SAFETY

1. PURPOSE. This Veterans Health Administration (VHA) Handbook defines procedures for the use of fluoroscopic imaging equipment that produces x-rays for diagnosis, localization, and guidance of interventional procedures. By use of these procedures, unnecessary radiation exposure to patients and health care workers is minimized and optimal image quality is achieved.

2. SUMMARY OF CHANGES. This is a new Handbook which addresses radiation safety, qualification of operators, technical quality control, device operation, shielding, dosimetry, and reporting of extreme exposures.

3. RELATED ISSUES. VHA Directive 1105 (to be published). ***NOTE:** Additional guidance on establishing a safety program for fluoroscopic imaging is issued by the VHA National Health Physics Program (10P4BHP) and can be found on their Web site http://nhpp.med.va.gov/NHPP_Diagnostic_Radiology_Info.asp.*

4. RESPONSIBLE OFFICES. The Radiology Program Office (10P4D) and the National Health Physics Program (10P4BHP) are responsible for the contents of this Handbook. Questions may be referred to (707) 562-8374 or (919) 383-7874 extension 260.

5. RESCISSIONS. None.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of July 2017.

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CONTENTS**FLUOROSCOPY SAFETY**

PARAGRAPHS	PAGE
1. Purpose	1
2. Background	1
3. Definitions	1
4. Scope	3
5. Responsibilities of the Medical Facility Director	3
6. Qualifications of Fluoroscope Operators	4
7. Safety Training	5
8. Standards for Protection Against Radiation	7
9. Radiation Safety Program	8
10. Equipment Specifications for Fluoroscopy Equipment	11
11. Technical Quality Assurance in Fluoroscopic Imaging	12
12. Records of Doses to Patients, Patient Follow-up, and Reporting of Sentinel Events	13
13. Procedures for Safe Use of Fluoroscopic Equipment	15
14. Structural Shielding	15
15. References	15
APPENDICES	
A Minimizing Radiation in Fluoroscopy	A-1
B Possible Clinical Effects from Fluoroscopic Exposures	B-1

FLUOROSCOPY SAFETY

1. PURPOSE

This Veterans Health Administration (VHA) Handbook defines safety procedures for the use of fluoroscopic imaging equipment that produces x-rays for diagnosis, localization, and guidance of interventional procedures.

2. BACKGROUND

a. Fluoroscopic imaging devices are an integral part of health care throughout the Department of Veteran Affairs (VA). Fluoroscopes are used by many services in a medical facility, including, but not limited to: radiology, cardiology, radiation oncology, orthopedic surgery, gastroenterology, vascular surgery, emergency management, anesthesiology, and urology. A fluoroscope generates a beam of x-rays that is directed through the patient onto a receptor to create real-time images. Fluoroscopy is used to view and record the motion of organs, passage of contrast material, and manipulation of devices. Procedures that employ fluoroscopy include upper and lower gastrointestinal studies, cardiac catheterization, catheter placement, biopsies, drainages, ablations, angioplasties, and arterial embolizations. Some fluoroscopes are capable of acquiring data about the patient from many projections to generate cross-sectional images.

b. A fluoroscope 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, typically associated with prolonged procedures or improper positioning of the patient, have caused skin burns, non-healing ulcers, and other tissue injuries to patients. A large dose of radiation to a fetus can cause developmental impairment, deformities, and impaired intelligence.

c. Unnecessary radiation exposure to patients and health care workers can be avoided by ensuring equipment is operating properly, staff follows proper procedures, shielding and engineered safety features are employed, and radiation doses are as low as reasonably achievable (ALARA).

d. 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 Handbook sets standards for the use of fluoroscopes.

3. DEFINITIONS

a. **Direct Supervision.** Supervision is direct if the supervisor is in the immediate vicinity of the person being supervised, defined as within the range of the normal human voice, and is aware of the procedure or examination in progress.

b. **Dose.** Dose means the absorbed radiation dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose (D) is the mean energy

imparted to matter in units of Joules, per unit of mass in units of kilograms, where the special name for the unit of absorbed dose is gray (Gy).

c. **Dose Area Product.** Dose area product is known as the kerma area product, a measure of dose times the area of skin irradiated.

d. **Fluoroscopy.** Fluoroscopy is the use of an x-ray imaging system to provide real-time x-ray projection images.

e. **Gray (Gy).** A Gy is a unit of absorbed dose and kerma (K) and is equal to 1 Joule per kilogram (1J/kg).

f. **Kerma (K).** 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.” Reference point air kerma is a quantity used to estimate skin dose where the reference point is the expected location of the skin for an average size patient.

g. **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.

(1) **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.

(a) Diagnostic radiological physicists design shielding for rooms housing x-ray imaging equipment and perform shielding acceptance surveys.

(b) Other duties commonly assigned to diagnostic radiological physicists include:

1. Design and review of technical quality control programs for x-ray imaging equipment;
2. Optimization of x-ray imaging protocols;
3. Calculations of the dose to the embryo or fetus when an x-ray imaging procedure was performed on a pregnant woman; and
4. Providing training to staff regarding the use of imaging equipment.

(2) **Therapeutic radiological physicists.** Therapeutic radiological physicists must be certified by the American Board of Radiology, the American Board of Medical Physics, or have similar qualifications. Therapeutic radiological physicists work to ensure the performance, calibration, use, and safety of equipment used in radiation therapy, including therapy devices and treatment planning systems.

(3) Medical health physicists. Medical health physicists must be certified by the American Board of Medical Physics, the American Board of Science in Nuclear Medicine, the American Board of Health Physics, or have similar qualifications. Medical health physicists often serve as the Radiation Safety Officer (RSO), 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.

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

i. **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.

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

4. SCOPE

This Handbook applies to all personnel employing fluoroscopy for imaging of humans at VA medical facilities. It provides mandatory requirements and guidance for the operation, quality assurance, and maintenance of fluoroscopic imaging devices used by any service within VHA. It addresses qualification of operators, technical quality control, device operation, shielding, dosimetry, and reporting of extreme exposures. By use of these procedures, unnecessary radiation exposure to patients and healthcare workers is minimized and optimal image quality is achieved.

5. RESPONSIBILITIES OF THE MEDICAL FACILITY DIRECTOR

If fluoroscopes are used by the facility, the Medical Facility Director is responsible for:

a. Appointing an RSO to direct the radiation safety program as described in paragraph 9 of this Handbook and providing the name of the RSO to the National Health Physics Program (NHPP).

b. Ensuring that a fluoroscopy safety training program is established and that such training is required in order to operate a fluoroscope (see par. 7).

c. Ensuring that personal dosimeters and radiation protective apparel are provided to persons operationally exposed to radiation in a work environment.

d. 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.

- e. Ensuring that fluoroscopes are tested by a medical physicist initially and yearly thereafter.
- f. Promoting a safety culture in which employees feel free to report radiation safety incidents and deficiencies.
- g. Ensuring top management is aware of important safety problems, and that deficiencies are corrected.
- h. Ensuring all precautions are taken for personnel and patient safety (see subpar. 9d and 9e).

6. QUALIFICATIONS OF FLUOROSCOPE OPERATORS

Personnel who operate fluoroscopes for imaging of patients are divided into two groups: physicians who may both operate the equipment and supervise non-physicians in the operation of fluoroscopes, and non-physicians who may operate fluoroscopes only under the direct supervision of a physician. The physician requirements are outlined in 6b and 6c, while non-physician requirements are covered in 6e through 6g.

a. **Qualifications for Staff Physicians.** A staff physician must have completed the training requirements detailed in paragraph 7 in order to perform fluoroscopy, or to directly supervise qualified non-physician personnel in the operation of a fluoroscope.

b. **Qualifications for Resident Physicians.** A resident physician may operate a fluoroscope, or may directly 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, and is supervised, directly or indirectly, by an attending physician who is privileged in fluoroscopy and who checks each study as specified by the facility resident supervision policy. Procedures that always require direct supervision of the resident for radiation safety purposes include any that have potential to exceed a skin dose of 3 Gy. Examples of potentially high-dose procedures are:

- (1) Cardiac catheterization;
- (2) Radiofrequency cardiac catheter ablation;
- (3) Vascular embolization;
- (4) Stent and filter placement;
- (5) Thrombolytic and fibrinolytic procedures;
- (6) Percutaneous transhepatic cholangiography;
- (7) Endoscopic retrograde cholangiopancreatography;
- (8) Transjugular intrahepatic portosystemic shunt;

- (9) Percutaneous nephrostomy;
- (10) Biliary drainage; or
- (11) Urinary or biliary stone removal.

c. **Qualifications for Diagnostic Radiologic Technicians (DRTs).** A Diagnostic Radiologic Technologist (DRT), General Schedule (GS) 647, may operate a fluoroscope under the direct supervision of a fluoroscopy-trained physician, but may not independently operate fluoroscopic equipment.

d. **Qualifications for Catheterization Medical Instrument Technician (CCMIT).** A Cardiac Catheterization Medical Instrument Technician (CCMIT), GS-649, may operate a fluoroscope during a cardiology procedure under the direct supervision of a fluoroscopy-trained cardiologist, but may not independently operate fluoroscopic equipment.

e. **Qualifications for Therapeutic Radiologic Technologists (TRT).** A Therapeutic Radiologic Technologist (TRT), GS-648, may operate a fluoroscope during a radiotherapy simulation procedure under the direct supervision of a fluoroscopy-trained radiation oncologist, but may not independently operate fluoroscopic equipment.

f. **Qualifications for Registered Nurses (RNs), Nurse Practitioners (NPs), and Physician Assistants (PAs).** Registered nurses, nurse practitioners, and physician assistants may operate fluoroscopes provided they have completed the training requirements detailed in paragraph 7, if the procedure is within their area of competency, and under the direct supervision of a physician trained in fluoroscopy. Examples include, but are not limited to:

- (1) 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; or
- (2) A nurse assigned to the gastrointestinal medicine service who centers a fluoroscopy tower and turns on the beam under the direction of a fluoroscopy trained gastroenterologist.

g. **Qualifications for Diagnostic Medical Physicists and Health Physicists.** A diagnostic medical physicist or medical health physicist is qualified to perform quality assurance testing of all fluoroscopes. A therapeutic medical physicist is qualified to perform quality assurance testing of fluoroscopes used in radiation oncology. ***NOTE: Board certification is strongly recommended for physicists who perform quality assurance testing.***

7. SAFETY TRAINING

a. **Training of Physicians**

- (1) Each physician who operates or directs the operation of fluoroscopic equipment for a medical procedure must be trained in fluoroscopy operation and safety to include: didactic lessons, hands-on-operation, and clinical operation under a preceptor physician.

(2) Didactic training need not be performed at or by the VA medical facility, provided that the trainee demonstrates: evidence of the date(s) of training; the name(s) of the person(s) providing the training; the topics included in the training; the duration of the training; the test questions, if available; and evidence of successful completion. Didactic training must include the following topics, with successful completion of a written examination:

- (a) Physics of x-ray production and interaction;
- (b) The technology of fluoroscopy machines, including modes of operation;
- (c) Characteristics of image quality and technical factors affecting image quality;
- (d) Dosimetric quantities and units;
- (e) Biological effects of radiation;
- (f) Principles of radiation protection in fluoroscopy;
- (g) Applicable Federal regulations and VHA requirements; and
- (h) Techniques for minimizing dose to the patient and staff.

(3) Hands-on training ideally needs to be conducted on the model of fluoroscope that is to be used. 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. **NOTE:** *Practitioners who regularly operate a fluoroscope at the time this policy is issued are considered to have met the requirements for hands-on and preceptor training.*

(4) Preceptor training consists of operation of the fluoroscope for clinical purposes under the supervision of a physician experienced in the operation of the device. Completion of this phase of training must include written confirmation, signed by the preceptor physician, that the individual has achieved a level of competency sufficient to function independently as a fluoroscopy operator. **NOTE:** *Practitioners who regularly operate a fluoroscope at the time this policy is issued are considered to have met the requirements for hands-on and preceptor training.*

(5) When considering the recommendation of privileges for a medical procedure that requires fluoroscopy, the Executive Committee of the Medical Staff (ECMS) must determine whether the physician's training meets these requirements. The ECMS may seek the opinion of an expert, such as the RSO, a medical physicist, or the Chief of Radiology in performing this task. **NOTE:** *In many medical facilities, the Professional Standards Board, the Medical Executive Committee, or the Clinical Executive Board is designated to act as the ECMS.*

(a) Training need only be undertaken once for purposes of meeting the requirements of this Handbook. However, this Handbook does not limit the ability of facility officers to prescribe additional training as is deemed necessary.

(b) Reasons for additional training could include, but are not limited to: If adoption of new fluoroscopic technology, high personal dosimetry approaching regulatory limits (see subpar. 8b), observation of poor practices, resumption of fluoroscopic procedures after a long period of inactivity, or need for periodic courses to refresh skills.

b. Training of Non-physicians

(1) Non-physician personnel who operate fluoroscopic equipment must undertake didactic, hands-on, and preceptor training. Training requirements for non-physicians differ from physicians only in that the preceptor may be either a physician privileged in fluoroscopy, or a DRT or a CCMIT who is trained to operate a fluoroscope.

(2) The medical facility Director must designate a qualified person(s) to evaluate whether training, received at the facility or elsewhere, meets these requirements.

(a) This individual will ordinarily be the RSO, a medical physicist, or the Chief of Radiology Service. This individual must issue a signed and dated form or memorandum stating the employee is qualified to operate fluoroscopes. Technologists who are American Registry of Radiologic Technologists (ARRT) certified in radiography or radiation therapy, or who are registered cardiovascular invasive specialists with Cardiovascular Credentialing International are considered to have met the didactic portion of the training requirement.

(b) Training need only be undertaken once for purposes of meeting the requirements of this Handbook. However, this Handbook does not limit the ability of facility officers to prescribe additional training as is deemed necessary.

c. **Records.** Records of training, and of signed preceptor statements, must be kept by the RSO. *NOTE: For information regarding records management, see VHA Directive 6300 for records control.*

8. STANDARDS FOR PROTECTION AGAINST RADIATION

a. **Exposure Standards, Generally.** 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 ALARA. Both the United States Occupational Safety and Health Administration (OSHA) and the United States Nuclear Regulatory Commission (NRC) establish standards for protection against radiation, which include: dose limits for staff and members of the public, requirements for the wearing of dosimeters, requirements for the posting of warning signs, and requirements for the reporting of excessive exposures to staff or members of the public.

(1) OSHA's regulations, in Title 29, Part 1910.1096, of the Code of Federal Regulations (CFR), apply to exposures from x-rays at VHA medical facilities.

(2) NRC regulations at 10 CFR Parts 19 and 20 pertain to exposures from radioactive material. However, when a person is exposed to both x-rays and radiation from radioactive material, the NRC's regulations pertain.

b. **Exposure Standards for Pregnant Women, Embryos, and Fetuses.** The dose equivalent from occupational exposure to the embryo or fetus of a woman who has voluntarily declared her pregnancy in writing 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. The facility must make changes in work assignments or work practices to meet this limit and must strive to avoid substantial variation above a uniform monthly exposure rate. This limit does not pertain to a female employee who has not declared pregnancy, nor does it apply to a pregnant employee who is herself a patient and must undergo a radiologic procedure. ***NOTE:** It is recommended that each female employee who works with x-ray generating machines be given a copy of NRC Regulatory Guide 8.13 or equivalent information so she is aware of her rights regarding radiation and pregnancy. **NOTE:** By setting the previously mentioned limit for fetal exposure, VA provides women and their fetuses' protection equivalent to that of most states, and equivalent to protection from radioactive sources by NRC.*

c. **Exposure Standards for Members of the Public.** 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. 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.

d. **Exposure Standards for Medical Purposes.** Humans may only be exposed to the primary radiation beams of fluoroscopic imaging equipment for medical purposes. Medical purposes include research involving the exposure of human subjects conducted in accordance with the Federal Policy for the Protection of Human Subjects. Humans may not be exposed to primary radiation solely for training, to test equipment, or to obtain images for accreditation.

e. **Reporting Requirements.** Each VHA facility must make notifications and reports regarding exposures to staff or members of the public that exceed regulatory limits to the VHA NHPP required by 10 CFR Part 20 and 29 CFR 1910.1096. Additionally, the NHPP must provide such reports to the NRC or to OSHA as required by each respective regulatory authority.

9. RADIATION SAFETY PROGRAM

a. **Objective.** The objective of medical use of ionizing radiation is to obtain optimum diagnostic information or therapeutic effect with minimum exposure to staff and members of the public and to minimize unnecessary irradiation of the patient. To this end, VHA establishes and adopts the rules and regulations as outlined in this paragraph. These rules and regulations contain the requirements for the protection and safety of all persons at or in the vicinity of ionizing radiation. These requirements must be met by all users of such ionizing radiation within the VHA system.

b. Designated RSO.

An RSO is designated by each facility Director using ionizing radiation for medical imaging. The RSO may communicate directly with facility executive management.

(1) For facilities that have a permit to use radioactive materials, the selection of RSO must be approved by the NHPP.

(2) For facilities that use diagnostic x-ray generating equipment, but do not have a permit for radioactive materials, the RSO needs to be a physicist, diagnostic radiology technologist, or a physician. The duties will usually be part-time.

c. RSO Duties. The duties of the RSO, with respect to fluoroscopy, are to:

(1) Establish and implement radiation safety procedures and to review them periodically to ensure their conformity with regulations, the requirements of this Handbook, and good radiation safety and medical physics practices.

(2) Instruct personnel in regulatory requirements, the requirements of this Handbook, and proper radiation protection practices before first working with radiation, or make available a course of instruction for same. A course in fluoroscopy safety that meets the requirements for didactic training may be found on the VA Talent Management System (TMS) with the course title “Minimizing Risks from Fluoroscopic X-rays.” **NOTE:** *VHA training is available at <https://www.tms.va.gov>.*

(3) Conduct or supervise radiation surveys where indicated and to keep records of such surveys and tests, including summaries or corrective measures recommended or instituted.

(4) Ensure that personal monitoring devices are used as required, that records are kept of the results of such monitoring, and to review the monitoring reports promptly to ensure that investigatory and regulatory limits are not exceeded. These records must be kept in a suitable organized file for the life of the facility. **NOTE:** *For information regarding records management, see VHA Directive 6300 for records control.*

(5) Ensure that required signs and notices are properly posted.

(6) Monitor compliance with the requirements of this Handbook.

(7) Promptly investigate each known or suspected case of excessive or abnormal exposure or misadministration, determine the causes, take steps to prevent its recurrence, and monitor such corrective actions.

(8) Ensure that required notifications and reports in the case of overexposures or personnel and sentinel events are submitted as required by this Handbook.

(9) Promptly notify facility Director, or designee, of significant safety hazards, significant violations of this Handbook, exposures of staff or members of the public that exceed regulatory requirements, and medical misadministrations.

(10) Review or have 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. Perform, or have a qualified expert perform, radiation surveys after installation but before clinical use of the equipment.

d. **Personnel Safety**

(1) Each person within the room where fluoroscopy is performed must wear a lead apron or garments providing equivalent protection. Shielded glasses or goggles and gloves must be made available as needed. 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.

(2) No visitor is allowed to be present in the room where fluoroscopy is performed, unless the visitor is a radiation worker present in an official capacity. If the patient is a child, the parent or guardian should ideally remain in the control room and not enter the fluoroscopy room, but may enter the fluoroscopy room wearing a lead apron at the discretion of the supervising physician.

(3) No employee or visitor is allowed to routinely expose themselves to radiation in order to position or restrain a patient during a procedure.

(4) The facility Director must supply personal dosimeters, must require the use of personal dosimeters by workers, and must maintain records of the doses received as required by 10 CFR 20 and 29 CFR 1910.1096. These records must be kept for the life of the institution. When a protective apron is worn, a dosimeter must be worn at the collar outside the apron. Alternatively, a dosimeter may be worn at the collar outside the apron and a second dosimeter may be worn on the abdomen under the apron. When multiple dosimeters are issued to an employee, each dosimeter must indicate the location on the body where it is to be worn.

(5) All personnel who work in the room where fluoroscopy is performed must undergo radiation safety training. Training must be provided 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 Handbook, facility requirements, methods for maintaining doses to staff within established limits and ALARA, and for protecting the patient.

e. **Patient Safety.** The facility Director must establish and implement:

(1) Procedures to ensure that the proper patient receives the intended examination or procedure. Procedures must require verification of the patient's identity by at least two methods. Precautions must be commensurate with the risk from the examination or procedure, with greater precautions being taken for procedures of greater risk.

(2) Procedures to determine, before conducting an examination or procedure, whether a female patient of childbearing age may be pregnant. These precautions must be equal with the risk from the examination or procedure to be performed, with greater precautions being taken for procedures imparting larger radiation doses to the abdomen or pelvic region of the patient.

(a) For procedures that may impart a dose to the embryo or fetus exceeding 0.1 Gy (10 rad), a serum pregnancy test must be obtained within 72 hours prior to the procedure and preferably the same or previous day, unless a physician determines that the delay caused by performing the test would harm the patient.

(b) The pregnancy test is not required if pregnancy can be ruled out by a documented hysterectomy or tubal ligation, postmenopausal state with absence of menstrual bleeding for 2 years, or by premenarche in a child.

(c) Procedures that may impart a dose to the embryo or fetus exceeding 0.1 Gy include prolonged fluoroscopic exposure to the abdomen or pelvis and computed tomography (CT) imaging involving more than two series through the abdomen or pelvis.

(d) 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.

(e) 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.

10. EQUIPMENT SPECIFICATIONS FOR FLUOROSCOPY EQUIPMENT

a. Each fluoroscopic system used in the VHA must conform to the performance specifications in 21 CFR Part 1020 that were in effect at the time of manufacture.

b. All fluoroscopes must display the cumulative fluoroscopy time, must have an audible signal that sounds after each 5 minutes of fluoroscopy time, and must be equipped with a last image hold capability which displays the last image after the production of radiation ceases. All fluoroscopic equipment manufactured on or after June 10, 2006, must display the air kerma rate and the cumulative air kerma at a reference point.

c. Specifications for acquisition of new fluoroscopes need to include:

(1) 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 position. These are the standard measures of patient radiation exposure.

(2) Support for Integrating the Healthcare 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.

11. TECHNICAL QUALITY ASSURANCE IN FLUOROSCOPIC IMAGING

a. **Technical Quality Assurance Program.** Each facility performing fluoroscopy must establish in writing and implement a technical quality assurance program that conforms to the “American College of Radiology Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiologic and Fluoroscopic Equipment.” The program must include all aspects of the imaging process from image acquisition through image display, including monitoring of the luminance and calibration of video monitors used for interpretation and the ambient viewing conditions in rooms used for image interpretation.

b. **Equipment Testing by a Medical Physicist.** The technical quality assurance program must include testing by a medical physicist of all imaging equipment producing x-rays. The equipment must be tested after installation, but before first clinical use, annually thereafter, and after each repair or modification that may affect patient dose or image quality. Testing after repair or modification must be performed before clinical use of the equipment. The testing, including a summary of methods, instruments used, measurements and deficiencies identified, must be documented in a written report signed by the medical physicist.

(1) The testing must include:

- (a) Measurement of radiation output parameters, including beam intensity and beam quality;
- (b) Testing of all modes of operation used clinically, including automatic exposure rate controls of fluoroscopy systems;
- (c) Assessment of image quality;
- (d) Assessment of technique factors used clinically;
- (e) Measurement of appropriate indices of patient dose or dose rates at typical clinical technique factors, with comparison to national standards;

(2) At the time of initial testing, conformance with purchase specifications; ***NOTE:*** *Acceptance testing performed by the VA National Acquisition Center does not eliminate the need for testing by a qualified medical physicist prior to first clinical use.*

(3) At the time of annual testing, review of the overall technical quality assurance program;

(4) Following repairs or modifications, testing may be limited to features and parameters that would be affected by the repairs or modifications.

c. The medical physicist may be assisted by other properly-trained persons in obtaining test data for performance monitoring. These individuals must be trained by the medical physicist in the techniques for performing the tests, the function, and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The medical

physicist must be present at the facility for the initial and annual testing and must promptly review, interpret, and approve all data measurements and test results.

d. When x-ray imaging equipment fails to meet the performance specifications in paragraph 10, the equipment must be promptly adjusted or repaired to correct the deficiency or must be removed from clinical use. A written record must be kept by the RSO of the correction of such deficiencies. The record must include the date of correction and the action taken to correct the deficiency. **NOTE:** *For information regarding records management, see VHA Directive 6300 for records control.*

e. If the review of clinically-used technique factors or the comparison of measured dose indices with national standards indicates that an optimum balance has not been achieved between patient dose and image quality or that the dose indices exceed national standards, the technique factors, whether posted in a chart or programmed into the fluoroscope, must be modified as necessary.

f. Appropriate indices of patient dose, measured by a medical physicist at clinically-used technique factors, must be posted near the controls of each fluoroscope. These indices include typical and maximal entrance skin dose or air kerma rate for each fluoroscopic mode of operation (e.g., pulse rate and magnification mode). For each image recording mode used clinically, these include the entrance skin dose or air kerma per image or the entrance skin dose or air kerma per second of imaging (e.g., cinefluorography in the cardiac catheterization laboratory) for a patient of typical thickness.

12. RECORDS OF DOSES TO PATIENTS, PATIENT FOLLOW-UP, AND REPORTING OF SENTINEL EVENTS

a. A record must be kept of each fluoroscopic procedure. The record can be made manually or electronically. **NOTE:** *For information regarding records management, see VHA Directive 6300 for records control.*

(1) If made manually, 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 directing the operation of the device. The record must also list the cumulative fluoroscopy time, number of static images, total time of dynamic cinefluorography (CINE) series, the cumulative air kerma or skin dose from both fluoroscopy and from static image recording, if available, and the dose-area-product, if available. The record must be kept in the custody of the Chief of Service 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. NOTE: For information regarding records management, see VHA Directive 6300 for records control.*

(2) Electronic 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 Structured Report (RDSR). Dose can be stored in a patient-identified dose registry, if such a registry is available. Dose of interventional cardiology procedures may be entered in the Clinical Assessment, Reporting, and Tracking System for Cardiac Catheterization Laboratories (CART-CL).

b. For each patient procedure in which the cumulative air kerma might exceed 3 Gy to any single location on the patient's skin, the deterministic risks of erythema and epilation must be discussed with the patient before the procedure begins.

c. An estimated peak skin dose must be calculated for procedures that may have exceeded 3 Gy. At the present time there is no technical means to conveniently calculate the dose at the skin site that received 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:

(1) Scattering of x-rays in the patient. Due to backscatter the true skin dose may be a factor of up to 1.4 times the displayed reference point air kerma.

(2) Use of multiple x-ray beam angles which 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, should be taken into account.

(3) Skin location that is closer to or farther from the x-ray tube than the reference point. 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. If 3 Gy skin dose to single field is exceeded, estimated skin doses and locations must be recorded in the patient's medical record.

e. If 3 Gy skin dose to a single field is exceeded, the patient must be instructed in self-examination of the skin for erythema and to report any radiation effects to the physician.

f. If 5 Gy skin dose to a single field is exceeded, 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 (see App. B).

g. If 5 Gy skin dose to a single field is exceeded, the RSO must be notified.

h. Any exposure that results in permanent skin damage is a sentinel event, and must be reported to the RSO and Patient Safety Manager.

i. 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. The Joint Commission interprets cumulative dose as the sum of doses over a 6 month to 1 year period.

j. 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.

13. PROCEDURES FOR SAFE USE OF FLUOROSCOPIC EQUIPMENT

Each medical facility must have a written policy for the safe use of fluoroscopic equipment that addresses safety of the patient, the operator, and nearby staff. The procedures for the safe use of fluoroscopic equipment are found in Appendix A, Minimizing Radiation in Fluoroscopy.

14. STRUCTURAL SHIELDING

a. 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. Structural shielding must be installed as necessary to maintain doses to persons in these areas ALARA and within regulatory limits.

b. For the structural shielding of rooms containing x-ray imaging devices, the shielding design goal must be 5 milligray (mGy) in a year to any person in a controlled area. For uncontrolled areas, the shielding design goal needs to be 1 mGy in a year to any person, and 0.02 mGy in any hour.

c. 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.

15. REFERENCES

a. **American Association of Physicists in Medicine (AAPM)**

(1) AAPM Report No. 58, *Managing the Use of Fluoroscopy in Medical Institutions*, 1998.

(2) AAPM Report No. 74, *Quality Control in Diagnostic Radiology* (Task Group 12), 2002.

b. **American College of Radiology (ACR)**

(1) ACR Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging

(2) ACR Technical Standard for the Diagnostic Technical Performance Monitoring of Radiographic and Fluoroscopic Equipment

(3) ACR Technical Standard for Management of Use of Radiation in Fluoroscopic Procedures

(4) ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation

c. **National Council on Radiation Protection and Measurement (NCRP)**

(1) NCRP Report No. 99, *Quality Assurance for Diagnostic Imaging*, 1988.

(2) NCRP Report No. 102, *Medical X-Ray, Electron Beam, And Gamma Ray Protection for Energies up to 50 mega electron volt (MeV) (Equipment Design, Performance, and Use)*, 1989.

(3) NCRP Report No. 147, *Structural Shielding Design for Medical X-Ray Imaging Facilities*, 2004.

(4) NCRP Report No. 168, *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures*, 2010.

d. **International Commission on Radiological Protection (ICRP)**

(1) ICRP Publication 84, *Pregnancy and Medical Radiation*, Pergamon, 2000.

(2) ICRP Publication 85, *Avoidance of Radiation Injuries from Medical Interventional Procedures*, Pergamon, 2000.

(3) ICRP *Statement on Tissue Reactions*, April 21, 2011.

e. **U.S. Food and Drug Administration (FDA)**

(1) Title 21 of the CFR, (FDA Regulations), Part 1000, Subpart C, Radiation Protection Recommendations.

(2) Title 21 of the CFR, (FDA Regulations), Part 1020, Performance Standards for Ionizing Radiation Emitting Products.

(3) Title 21 of the CFR, (FDA Regulations), Part 803, Medical Device Reporting.

(4) FDA, *Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures*, September 9, 1994.

(5) 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.

f. **Other**

(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) 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.

(3) 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.

(4) Balter S, Hopewell JW, Miller DL, et al. *Fluoroscopically Guided Interventional Procedures:*

(5) *A Review of Radiation Effects on Patients' Skin and Hair*. Radiology 2010; 254: 326-341.

(6) Stecker MS, Balter S, Towbin RB, et al. *Guidelines for Patient Radiation Dose Management*.

(7) Journal of Vascular and Interventional Radiology 2009; 20:S263–S273.

MINIMIZING RADIATION IN FLUOROSCOPY

The procedures for the safe use of fluoroscopic equipment are listed in this Appendix.

1. VHA Medical Facility Staff Protection

a. VHA medical facility staff are required to wear dosimeters as directed by facility policy. Either a single dosimeter must be worn at the collar outside the apron, or a dosimeter may be worn at the collar outside the apron and a second one on the front of the torso underneath the apron. A finger dosimeter may optionally be worn on the hand receiving the greatest dose.

b. Protective apparel must provide at least 0.5 millimeters (mm) lead equivalent shielding on the front and wear a thyroid shield. Staff in the room whose sides or backs may be exposed to scatter must wear aprons providing at least 0.25 mm lead equivalent on the sides and backs.

c. Transparent radiation shields need to be worn 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 enters the patient. The operator may wear leaded glasses, goggles, or a full-face shield that provide radiation shielding if a transparent radiation shield is not used. Protective eyewear must provide shielding from scattered x-rays from the side and below, because the operator is commonly looking at the monitor while x-rays are generated.

d. 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, stand on the image receptor side of the patient instead of on the x-ray tube side.

e. Medical facility staff must keep unshielded hands out of the primary beam. When manipulating devices in the beam such as biopsy needles, they need to use forceps. If medical facility staff must place their hands in the beam they must wear leaded gloves.

f. To minimize exposure, the fluoroscopy operator must stand as far from the exposure site as possible. Avoid bringing your face close to the exposed field as this may result in cataracts. Nurses must avoid sitting or standing near the patient unless they are making a patient assessment.

g. X-ray tubes must be placed below or on the far side of the patient whenever possible so scattered radiation will be predominantly directed away from the body of the operator.

2. Patient Protection

a. X-ray tubes must be kept as far from the patient as possible. Do not remove the spacer device from a c-arm fluoroscope because that allows the x-ray source to be brought too close to 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.

APPENDIX A

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 need to collimate the x-ray beam to the smallest area consistent with clinical needs.

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

e. Fluoroscopy operators need to limit the number of images recorded to the minimum that are clinically necessary.

f. When recording dynamic image sequences (e.g., cinefluorography) fluoroscopy operators need to use the lowest frame rate that is clinically acceptable. In cardiac catheterization laboratories, a frame rate of 15 images per second is commonly used for studies of the adult heart.

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

h. In manual mode, fluoroscopy operators need to 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 need to 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 will not harm image quality, such as small patients and when there is a large gap between the patient and the image receptor.

k. Fluoroscopy operators need to 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. Fluoroscopy operators must shield organs of the patient that are particularly radiation sensitive, such as the gonads and eyes, when they must be in the primary beam and such shielding will not compromise the clinical procedure. The shielding must be placed on the x-ray source side of the patient.

m. For long procedures, fluoroscopy operators need to vary projection angles to avoid skin injuries.

n. Fluoroscopy operators need to be aware that dose to the patient's skin and to staff accumulates much more rapidly in obese patients.

3. Patient Screening

a. Fluoroscopy operators must determine, before each procedure, whether female patients of reproductive age may be pregnant. Special consideration must be given to protection of the embryo or fetus of a female patient known to be pregnant.

b. Fluoroscopy operators must determine, before each potentially high-dose procedure, whether the patient has any conditions that might significantly lower the threshold for radiation injury. These include previous large radiation doses to the same part of the body from fluoroscopy or radiation oncology; certain rare hereditary diseases affecting deoxyribonucleic acid (DNA) repair, such as ataxia telangiectasia; hyperthyroidism and diabetes mellitus; certain autoimmune and connective tissue disorders; and certain drugs, including actinomycin D, bleomycin, doxorubicin, 5-fluorouracil, and methotrexate (see par. 15c).

4. Operator Training

a. Persons operating the fluoroscope and persons directing its operation must be trained and authorized by the facility in its use.

b. Persons operating the fluoroscope and persons directing its operation must learn the functions of and use the dose optimizing modes available on the particular fluoroscope.

c. Persons operating the fluoroscope and persons directing its operation must compose a checklist of procedure steps in order to minimize procedure time.

5. Documentation and Follow-Up

a. If the patient's estimated skin dose exceeds 3 Gy, the physician performing the procedure or their designee must document the beam entrance skin locations and estimated doses to each in the patient's medical record.

b. If patient's estimated skin dose exceeds 5 Gy, the physician performing the procedure must arrange for patient follow-up as appropriate to the dose and notify the RSO.

6. Guidelines for CT Imaging with Fluoroscopy Systems

a. Only individuals whose presence is necessary will be allowed in the room while images are acquired. These individuals must be shielded from radiation by means such as protective aprons or portable shields and need to maintain as much distance as possible from where the x-ray beam intersects the patient.

- b. Fluoroscopy operators need to limit the number of CT imaging sequences to the minimum that are clinically necessary.
- c. Fluoroscopy operators must use technique factors that produce a clinically adequate image instead of an ideal image.
- d. Fluoroscopy operators must adjust technique factors for the size of the patient and the body part being imaged. In particular, adult technique factors must not be used for children and infants.

POSSIBLE CLINICAL EFFECTS FROM FLUOROSCOPIC EXPOSURES

1. After an interventional fluoroscopic procedure, there are a number of radiation skin effects of varying severity that may occur. It is important that the physician performing high-dose fluoroscopic procedures be aware of the potential for these skin effects. Appropriate information must be communicated to the patient regarding where to look for skin changes and how they appear.
2. 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.
3. 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. Doses in the range of 5-10 Gy can cause itching, partial or permanent epilation and prolonged erythema and ultimately skin telangiectasia and atrophy. 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.
4. 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.

Typical deterministic effects as a function of skin exposure:

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
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.
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.

From 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

Recommended follow-up as a function of skin exposure:

Skin Dose (Gy)	Advice to Patients and Treating Physicians
0 – 2	No need to inform patient, because there should be no visible effects. If patient reports skin changes, then treat in response to the signs and symptoms.
2 – 5	Advise patient that erythema may be observed, but should fade with time. Advise patient to call you if skin changes cause physical discomfort.
5 – 10	Arrange for examination of patient approximately 4 to 8 weeks after the procedure. Tell patient where skin effects would most likely occur. If skin erythema and itching occur, patient should call the physician's office. Skin reactions are often treated conservatively. Might advise the patient to be examined by dermatologist or other treating physician. Inform the treating physician that injury may be due to radiation and communicate expected location of radiation-related skin effects.
10 – 15	Medical follow-up is appropriate. Advise dermatologist or other treating physician that skin effects may be prolonged due to radiation dose and that prophylactic treatment for infection and monitoring of wound progression may be required. Pain could become a concern if doses are in the higher end of this range. Skin biopsy may result in skin breakdown and should be avoided.
> 15	Medical follow-up is essential, the nature and frequency of which depending on estimated radiation dose. Advise treating physician that the wound could progress to ulceration or necrosis.

Revised from 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.