

FLUOROSCOPY SAFETY

1. SUMMARY OF MAJOR CHANGES: Major changes are as follows:

a. Paragraph 2:

(1) Clarifies optimization of dose to the patient and fluoroscopic protocol requirements.

(2) Clarifies criteria for Chief, Department of Veterans Affairs (VA) medical facility Healthcare Technology Management Service and Diagnostic Medical Physicist inspection of fluoroscopic equipment following repair services or modifications.

(3) Defines and differentiates responsibilities between independent and dependent fluoroscope operators.

(4) Adds requirements for use of fluoroscopy in research.

(5) Allows for use of more current radiation dose metrics (e.g., peak skin dose) if available.

(6) Adds requirements for VA medical facility Health Professions Trainee (HPT) Program Directors regarding evaluating competencies of HPTs for the performance of fluoroscopy.

b. Paragraph 3: Adds requirements regarding the performance of fluoroscopic procedures by HPTs.

c. Paragraph 4: Updates fluoroscopy training requirements:

(1) Modifies requirements for initial training of fluoroscope operators to state that required hands-on training and preceptor training may be accomplished during the post-privileging period. Hands-on training is required before first clinical use of the fluoroscope, and preceptor training may be performed in the initial part of the Focused Professional Practice Evaluation for new privileges.

(2) Requires refresher training every 2 years.

(3) Updates requirements for Registered Radiologist Assistants.

(4) Adds requirements for the training of HPTs.

d. Paragraph 7: Adds definitions for HPT, optimization of dose to the patient, sentinel event and significant radiation-related injury.

e. Converts former Appendices A-E into four standard operating procedures (SOPs) on the National Radiology Program SharePoint site at: <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

f. Removes the requirement in former Appendix A for VA medical facilities to create a local policy to determine whether a patient of childbearing age may be pregnant; instead, VA medical facilities must develop precautionary procedures.

2. RELATED ISSUES: VHA Directive 1063(2), Utilization of Physician Assistants (PA), dated December 24, 2013; VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015; and VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.

3. POLICY OWNER: The Executive Director, Veterans Health Administration (VHA) National Radiology Program (11DIAG1) and the Executive Director, VHA National Health Physics Program (11SPEC12) are responsible for the contents of this directive. Questions may be referred to VHARadiologyProgramOffice@va.gov.

4. LOCAL DOCUMENT REQUIREMENTS: There are no local policy or SOP creation requirements in this directive.

5. RESCISSION: VHA Directive 1105.04, Fluoroscopy Safety, dated June 21, 2018, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of December 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Erica M. Scavella MD, FACP, FACHE
Assistant Under Secretary for Health
for Clinical Services/CMO

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. POLICY

It is Veterans Health Administration (VHA) policy that all Veterans receiving fluoroscopic imaging, Department of Veterans Affairs (VA) health care employees performing or participating in fluoroscopic imaging procedures, non-participating VA employees and the general public in VA medical facilities receive radiation exposures that are as low as reasonably achievable (ALARA) and that patients whose radiation doses from individual procedures exceed specified values receive appropriate clinical follow-up. **NOTE:** *The scope and intent of this directive is to outline the standards and requirements for fluoroscopy safety in VHA. This directive does not address the standards for competency and proficiency in the interpretation of still or cine based radiographic images derived from fluoroscopic examinations.* **AUTHORITY:** 38 U.S.C. § 7301(b).

2. RESPONSIBILITIES

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

b. **Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer.** The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer is responsible for supporting the VHA National Radiology Program (NRP) and the VHA National Health Physics Program (NHPP) with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer is responsible for supporting Patient Care Services program offices with implementation of this directive.

d. **Chief Operating Officer.** The Chief Operating Officer is responsible for:

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

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

e. **Chief Officer, Specialty Care Program Office.** The Chief Officer, Specialty Care Program Office is responsible for supporting the Executive Director, NHPP, in executing their responsibilities as outlined in this directive.

f. **Executive Director, VHA National Radiology Program.** The Executive Director, VHA NRP is responsible for:

(1) Overseeing VISN and VA medical facility compliance with this directive and ensuring corrective action is taken when non-compliance is identified.

(2) Coordinating with the Executive Director, VHA NHPP to evaluate technological changes in fluoroscopy and changes in accrediting agency standards and update this directive as needed.

g. **Executive Director, VHA National Health Physics Program.** The Executive Director, VHA NHPP is responsible for:

(1) Assisting the Executive Director, VHA NRP in overseeing VISN and VA medical facility compliance with this directive and ensuring corrective action is taken when non-compliance is identified.

(2) Coordinating with the Executive Director, VHA NRP to evaluate technological changes in fluoroscopy and changes in accrediting agency standards and update this directive as needed.

(3) Collaborating with VA medical facility Quality Managers and Radiation Safety Officers (RSOs) to investigate sentinel events, significant radiation-related injuries to patients and other radiation-related adverse events when notified by the VA medical facility Director, and reporting them to the National Radiation Safety Committee (NRSC) and to the relevant national clinical program director. **NOTE:** See paragraph 7 for definitions of sentinel event and significant radiation-related injury.

h. **Chair, National Radiation Safety Committee.** The Chair, NRSC is responsible for:

(1) Ensuring that the NRSC tracks and reviews sentinel events, radiation-related injuries to patients and other radiation-related adverse events resulting from fluoroscopic imaging, including ensuring that root cause analyses (RCAs) were performed at the VA medical facility and that the identified causes and actions taken appear appropriate.

(2) Ensuring that the NRSC reviews and endorses any modifications to the mandatory standard operating procedures (SOPs) 1105.04-01 through 1105.04-04 available on the NRP SharePoint site at:

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

i. **Chair, Institutional Review Board.** The Chair, Institutional Review Board (IRB) is responsible for:

(1) Ensuring that all research protocols approved by the IRB which involve a fluoroscopic procedure have undergone review and approval of the fluoroscopic

component of the research protocol by the VA medical facility Radiation Safety Committee (RSC).

(2) Ensuring that continuing reviews of research protocols involving fluoroscopic procedures have documentation of reporting of fluoroscopic doses to the VA medical facility RSC.

j. **Veterans Integrated Services Network Director.** The VISN Director is responsible for ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

k. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and mandatory SOPs 1105.04-01 through 1105.04-04 available on the NRP SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>, and that appropriate corrective action is taken if non-compliance is identified. **NOTE:** *This is an internal VA website that is not available to the public.*

(2) Appointing in writing, and ensuring continuous appointment of, a VA medical facility RSO to direct the radiation safety program and providing their name to the Executive Director, VHA NHPP. **NOTE:** *See VHA Directive 1105, Management of Radioactive Materials, dated February 24, 2021, and VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015, for requirements regarding the VA medical facility RSO.*

(3) Establishing a VA medical facility RSC. **NOTE:** *See VHA Directive 1105 and VHA Directive 1129 for requirements regarding the VA medical facility RSC.*

(4) Ensuring that a fluoroscopy safety training program is established in compliance with the requirements of this directive and that such training is required to operate a fluoroscope for both VA medical facility independent and dependent fluoroscope operators. This includes a credentialing and privileging process with validation that initial didactic fluoroscopy training has occurred as part of credentialing. The post-privileging process includes a Focused Professional Practice Evaluation (FPPE) period during which the fluoroscope operator receives initial hands-on training prior to first use of the fluoroscope and completes successful preceptor training in their initial use of the equipment. **NOTE:** *See paragraph 4 for additional information about training.*

(5) Ensuring that all VA medical facility independent fluoroscope operators meet the requirements of this directive through the credentialing and privileging process.

(6) Ensuring that personal dosimeters and radiation protective apparel are provided to persons operationally exposed to radiation in a work environment in accordance with VHA Directive 1129 and VHA Directive 1105.

(7) Ensuring that fluoroscopes are used in rooms with structural shielding as necessary to prevent radiation exposure from exceeding allowed limits to employees

and the public in adjacent spaces. **NOTE:** *This may not be possible in limited-use settings such as an Intensive Care Unit room. This, however, does not eliminate the requirement for appropriate shielding in rooms where fluoroscopy (including mobile fluoroscopy) is routinely conducted. See National Council on Radiation Protection and Measurements (NCRP) Report No. 147, Structural Design for Medical X-Ray Imaging Facilities, at <https://ncrponline.org/?s=report+147>.*

(8) Promoting a safety culture where employees feel free to report radiation safety incidents and deficiencies without fear of reprisal.

(9) Ensuring that the VA medical facility implements a technical quality assurance program that complies with hospital accreditation standards regarding ionizing radiation in medical imaging and conforms substantially to the elements in Appendix A of the American College of Radiology-American Association of Physicists in Medicine Technical Quality Assurance in Fluoroscopic Imaging (<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Fluoro-Equip.pdf>). **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.*

(10) Ensuring that a VA medical facility Diagnostic Medical Physicist performs testing as soon as feasible and no later than 30 days after initial installation of fluoroscopic equipment, following major repairs and annually. **NOTE:** *For requirements on this inspection, see VHA Directive 1129.*

(11) Ensuring that appropriate staff at the VA medical facility record doses to patients, review patient doses as part of the clinical quality assurance program, perform patient follow-up and report sentinel events, significant radiation-related injuries to patients and other radiation-related adverse events. **NOTE:** *For more information about recording and reviewing doses to patients and patient follow-up, see the mandatory SOP 1105.04-02, Monitoring for Clinical Effects of Fluoroscopic Procedures: Records and Reporting, Patient Counseling and Follow-Up, on NRP's SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. This is an internal VA website that is not available to the public.*

(12) Reporting to the Executive Director, VHA NHPP any sentinel events, significant radiation-related injuries to patients and other radiation-related adverse events at the time of identification in accordance with SOP 1105.04-02, Monitoring for Clinical Effects of Fluoroscopic Procedures: Records and Reporting, Patient Counseling and Follow-Up, on NRP's SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>; ensuring RCAs are performed to understand the underlying cause of the event; and taking appropriate action to address it. If a VA medical facility reports to an accrediting organization (e.g., The Joint Commission) a sentinel event involving fluoroscopy, they must also notify NHPP. **NOTE:** *This is an internal VA website that is not available to the public.*

(13) Reviewing and approving VA medical facility RSC meeting minutes not more than 45 days after the date of the meeting as described in VHA Directive 1105.

I. VA Medical Facility Chief of Staff and Associate Director for Patient Care Services. The VA medical facility Chief of Staff (CoS) and Associate Director for Patient Care Services (ADPCS) who has licensed independent practitioners (LIPs) under their supervisory authority who are independent fluoroscope operators are responsible for:

(1) Reviewing VA medical facility RSC meeting minutes prior to final approval by the VA medical facility Director.

(2) Ensuring that all LIPs credentialed and privileged to perform fluoroscopy complete initial and ongoing training requirements.

(3) Ensuring privileging forms contain a separate privilege for “fluoroscopy operation and safety” for qualified members of the medical staff to allow them to operate as independent fluoroscope operators.

m. VA Medical Facility Radiation Safety Officer. The VA medical facility RSO is responsible for:

(1) Monitoring compliance in all VA medical facility services and sections with this directive and the mandatory SOPs 1105.04-01 through 1105.04-04 on NRP’s SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx> to ensure their conformity with Federal radiation safety regulations and this directive, and notifying the VA medical facility Director, VA medical facility Chief of Staff and Chair, VA medical facility RSC when significant non-compliance is identified.

NOTE: *This is an internal VA website that is not available to the public. A VA medical facility may implement local procedures to supplement these SOPs if necessary.*

(2) Collaborating with VA medical facility service, division or section chiefs and the VA medical facility RSC to ensure optimization of dose to the patient in fluoroscopy is incorporated into a VA medical facility clinical quality program. ***NOTE:*** *For example, this could include collaboration with the Radiology Quality Assurance/Quality Improvement Committee or the VA medical facility Quality Manager.*

(3) Ensuring that regulatory standards for radiation safety and medical physics practices are followed throughout the VA medical facility in accordance with VHA Directive 1105 and VHA Directive 1129.

(4) Ensuring that VA medical facility employees are instructed regarding requirements of this directive, Federal radiation safety regulations applicable to fluoroscopy and proper radiation protection practices before first working with Fluoroscopy. ***NOTE:*** *For additional information about radiation protection practices, see the SOP 1105.04-03, Protection of Staff and Members of the Public, on NRP’s SharePoint site at*

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. This is an internal VA website that is not available to the public.

(5) Ensuring that individuals who are required to complete fluoroscopy training are identified.

(6) Collaborating with the VA medical facility medical staff office (i.e., Credentialing and Privileging) to ensure maintenance of records of employee training and signed preceptor statements that are required by this directive regarding VA medical facility independent fluoroscope operators. **NOTE:** For information regarding records management, see paragraph 5 and VHA Directive 6300(1), Records Management, dated October 22, 2018.

(7) Evaluating and certifying in writing, in conjunction with the VA medical facility RSC and VA medical facility service, division or section chiefs and in collaboration with the medical staff office director, whether the training received at the VA medical facility or elsewhere, meets the requirements to be a VA medical facility independent fluoroscope operator as defined in this directive. **NOTE:** This directive does not limit the ability of VA medical facility RSC to require additional training as deemed necessary.

(8) Conducting or supervising radiation surveys where required (e.g., upon installation of new fluoroscopic equipment) to ensure radiation transmitted outside of procedure rooms does not exceed dose limits and shielding design goals in NCRP Report No. 147 and keeping records of such surveys and tests, including summaries or corrective measures recommended or instituted. The VA medical facility RSO must provide these summary reports of radiation surveys to the VA medical facility RSC.

(9) Ensuring that personal monitoring devices are issued as required by 29 C.F.R. § 1910.1096 and 10 C.F.R. Part 20 if applicable, records are kept of the results of such monitoring, reports are reviewed within 30 days of receipt to ensure doses are ALARA and regulatory limits are not exceeded, and results are reported to affected staff at least annually. **NOTE:** Non-compliance with the use of required personal monitoring device must be reported to the individual's supervisor for the appropriate remediation.

(10) Ensuring that required ionizing radiation signs and notices are properly posted on fluoroscopic procedure rooms in accordance with VHA Directive 1105 and VHA Directive 1129.

(11) Notifying the Chair, VA medical facility RSC of significant safety problems and that reporting requirements are followed as outlined in the SOP 1105.04-02, Monitoring for Clinical Effects of Fluoroscopic Procedures: Records and Reporting, Patient Counseling and Follow-Up, on NRP's SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

(12) Notifying the VA medical facility Director, VA medical facility Chief of Staff and Chair, VA medical facility RSC at the time of identification if any of the following occur:

(a) Sentinel events.

(b) Significant injuries to patients, other radiation-related adverse events, safety hazards and significant violations of this directive.

(c) Exposures of staff or members of the public that exceed regulatory limits or the limits imposed by this directive and VHA Directive 1129. **NOTE:** *For the most updated regulatory requirements, see 29 C.F.R. § 1910.1096 and 10 C.F.R. Part 20.*

(13) Ensuring at least quarterly periodic review of patient exposure metrics by the clinical services that utilize fluoroscopy, including cases where substantial radiation dose levels (SRDLs) are exceeded.

(14) Prior to construction, ensuring that a qualified expert reviews plans for rooms where ionizing radiation producing equipment will be installed, including room layout, structural and in-room shielding, viewing and communications systems.

(15) Ensuring that a qualified expert completes a structural shielding design for new construction of fluoroscopic imaging suites and before replacement of equipment as specified by NCRP Report No. 147, Structural Design for Medical X-Ray Imaging Facilities, at <https://ncrponline.org/?s=report+147>, and documents the evaluation in a written report.

(16) Ensuring that a qualified expert performs radiation surveys after installation but before clinical use of the equipment. **NOTE:** *See paragraph 7 for a definition of qualified expert. 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 Diagnostic Medical Physicist or Medical Health Physicist.*

(17) In coordination with the clinical service utilizing fluoroscopy and the Chief, VA medical facility HTM Service, ensuring that a Diagnostic Medical Physicist completes inspection of fluoroscopic equipment as soon as feasible and within 30 days following initial installation or major repairs that could change dose output or affect image quality. **NOTE:** *For more information on inspection requirements, see VHA Directive 1129.*

(18) Collaborating with the VA medical facility Health Professions Trainee (HPT) Program Director (PD) regarding the status of competency evaluations for HPTs (see paragraphs 3 and 4).

n. **Chair, VA Medical Facility Radiation Safety Committee.** **NOTE:** *For additional VA medical facility RSC responsibilities, see VHA Directives 1105 and 1129. The Chair, VA medical facility RSC is responsible for ensuring that the VA medical facility RSC performs the following functions:*

(1) Monitoring overall VA medical facility radiation safety program compliance with this directive and SOPs 1105.04-01 through 1105.04-04 available on the NRP SharePoint site at

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>, and that appropriate corrective action is taken if non-compliance is identified. **NOTE:** *This is an internal VA website that is not available to the public.*

(2) Collaborating with the VA medical facility RSO and VA medical facility service, division or section chiefs to ensure fluoroscopic dose optimization is incorporated into a VA medical facility technical and clinical quality program.

(3) At a minimum of twice a year, providing the VA medical facility CoS (via the VA medical facility RSC meeting minutes or report to the Medical Executive Committee or equivalent) with reports on safe use of fluoroscopy for patients and staff and compliance with this directive, including required training.

(4) Reviewing summary reports of radiation surveys provided by the VA medical facility RSO and ensuring resolution of any corrective measures identified.

(5) Reviewing and approving or disapproving the fluoroscopic component of research protocols approved by the IRB which involve a fluoroscopic procedure.

(6) Reviewing, at least twice annually, dose data from research protocols with a fluoroscopic component.

(7) Ensures that all research protocols involving the use of fluoroscopy that are approved by the RSC meet the requirements of the Federal Policy for the Protection of Human Subjects (see 45 C.F.R. Part 46 and 38 C.F.R. Part 16) and the requirements of this directive.

(8) Reviewing that training requirements have been met and approving recommended appointments for VA medical facility dependent fluoroscope operators. The VA medical facility Chair, RSC, and RSO may jointly approve such recommended appointments on an interim basis; such an interim approval is valid until the next routine meeting of the RSC. The RSC must maintain (e.g., in meeting minutes) a written record of appointments.

o. **VA Medical Facility Quality Manager.** The VA medical facility Quality Manager is responsible for working with the VA medical facility RSO and RSC when a sentinel event, significant radiation-related injury to a patient or other radiation-related adverse event occurs.

p. **VA Medical Facility Service, Division or Section Chief.** The VA medical facility service, division or section chief of any clinical service that utilizes fluoroscopy (e.g., Radiology, Cardiology, Surgery, Pain Management) is responsible for ensuring compliance with this directive within their service, division or section and specifically for:

(1) Collaborating with the VA medical facility RSO and VA medical facility RSC to ensure fluoroscopic dose optimization is incorporated into service or VA medical facility clinical quality management programs. Examples may include development of SOPs that optimize the use of dose saving equipment functionality, procedure-specific device

settings in the form of a checklist or alternatively programmed as default fluoroscope settings.

(2) Establishing and implementing procedures for recording metrics of radiation dose to the patient for each procedure in a format such as a spreadsheet or database suitable for quality assurance review by the clinical service.

(3) At least quarterly, reviewing radiation dose administration metrics, including cases where SRDLs are exceeded, with communication of any pertinent recommendations to the VA medical facility RSC. **NOTE:** For additional information, see the mandatory SOP 1105.04-02, *Monitoring for Clinical Effects of Fluoroscopic Exposures: Records and Reporting, Patient Counseling and Follow-Up*, on NRP's SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. This is an internal VA website that is not available to the public.

(4) Ensuring that the service or section has written procedures as needed in accordance with this directive and SOPs 1105.04-01 through 1105.04-04 on NRP's SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

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

(6) Ensuring appropriate safeguards for pregnant and possibly pregnant patients. **NOTE:** See SOP 1105.04-01, *Patient Safety Actions Before, During and After Fluoroscopy*, and SOP 1105.04-03, *Protection of Staff and Members of the Public*, at NRP's SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx> for more information. This is an internal VA website that is not available to the public.

(7) Ensuring that all health care providers requesting privileges for procedures which involve use of fluoroscopy have successfully met the initial fluoroscopic training requirements and apply for a separate privilege in fluoroscopy. See paragraph 4.a. for additional information about initial training.

(8) Ensuring that all personnel who work in the room where fluoroscopy is performed undergo radiation safety refresher training at least every 2 years. **NOTE:** The training must be commensurate with risk to the staff and must cover the risks from exposure to ionizing radiation, pertinent requirements of this directive, methods for protecting the patient and ensuring doses to staff are ALARA and within established limits. See paragraph 4 for additional information about training.

(9) Identifying VA medical facility fluoroscopy support staff and ensuring they receive training appropriate to these duties (see paragraph 4).

(10) Maintaining a list of VA medical facility dependent fluoroscope operators within their service or section and communicating this list and any updates to the VA medical facility RSO.

(11) Ensuring that staff performing or assisting with fluoroscopy who are provided dosimeters wear them properly.

(12) In coordination with the Chief, VA medical facility Healthcare Technology Management (HTM) Service and the VA medical facility RSO, ensuring that a Diagnostic Medical Physicist completes inspection as soon as feasible and within 30 days following initial installation or major repairs of fluoroscopic equipment that could change dose output or affect image quality. **NOTE:** *For more information on inspection requirements, see VHA Directive 1129.*

(13) Recommending staff appointments as VA medical facility dependent fluoroscope operators to the RSC in writing for approval. The written recommendation must confirm that initial training requirements have been met.

(14) Ensuring that when a new fluoroscopy system is installed or introduced, a review of imaging protocols occurs to select appropriate protocols for common clinical procedures and to validate image quality and appropriateness of radiation doses to patients, and creating a pre-procedure checklist for initial fluoroscope settings for each common clinical procedure.

q. **Chief, VA Medical Facility Healthcare Technology Management Service.** The Chief, VA medical facility HTM Service is responsible for:

(1) In coordination with the VA medical facility service, division or section chief of the clinical service utilizing fluoroscopy and the VA medical facility RSO, ensuring that a Diagnostic Medical Physicist completes inspection as soon as feasible and within 30 days following initial installation or major repairs of fluoroscopic equipment that could change dose output or affect image quality. **NOTE:** *For more information on inspection requirements, see VHA Directive 1129.*

(2) Ensuring restoration of fluoroscopic equipment back to the manufacturer's specifications prior to first patient use following repairs or service that could affect dose output or image quality.

r. **VA Medical Facility Health Professions Trainee Program Director.** The VA medical facility HPT PD is responsible for:

(1) Evaluating and maintaining records of competencies of HPTs for the performance of fluoroscopy in accordance with the competency assessment located at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.* For additional detail, see paragraphs 3 and 4.

(2) Collaborating with the VA medical facility RSO regarding the status of competency evaluations for HPTs.

s. **VA Medical Facility Diagnostic Medical Physicist.** *NOTE: VA medical facility medical physicists are physicists working in medicine. Three medical physics specialties that may be involved in fluoroscopy are: Diagnostic Medical Physicists, Therapeutic Radiological Physicists and Medical Health Physicists. The Diagnostic Medical Physicist is responsible for performing testing of new fluoroscopic equipment as soon as feasible and no later than 30 days after initial installation of fluoroscopic equipment, following major repairs that could change dose output or affect image quality and annually.* ***NOTE: For more information on inspection requirements, see VHA Directive 1129.***

t. **VA Medical Facility Principal Investigator, Fluoroscopy Research Protocol.** The VA medical facility Principal Investigator, Fluoroscopy Research Protocol is responsible for:

(1) Ensuring that a VA medical facility independent fluoroscope operator, when participating as part of the research team, performs the fluoroscopic portion of the research protocol or provides supervision to a VA medical facility dependent fluoroscope operator in its performance.

(2) Ensuring reporting of individual research procedure dose data to the VA medical facility RSC on at least a quarterly basis.

u. **VA Medical Facility Independent Fluoroscope Operator.** VA medical facility independent fluoroscope operators are appropriately trained and credentialed physicians, podiatrists and certified nurse practitioners and other LIPs who have privileges to independently perform or supervise fluoroscopic exams or procedures. For qualifications of VA medical facility independent fluoroscope operators, see the mandatory SOP 1105.04-04, Qualifications of Fluoroscope Operators and Levels of Supervision, on NRP's SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. ***NOTE: This is an internal VA website that is not available to the public.*** A VA medical facility independent fluoroscope operator is responsible for the following, which may be delegated all or in part to alternate staff members with appropriate supervision:

(1) Ensuring care for the patient before, during and after fluoroscopic procedures and providing follow-up related to possible fluoroscopically related patient issues.

NOTE: See mandatory SOP 1105.04-01: Patient Safety Actions Before, During and After Fluoroscopy, and SOP 1105.04-02, Monitoring for Clinical Effects of Fluoroscopy Exposures: Records and Reporting, Patient Counseling and Follow-Up, on NRP's SharePoint site at

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. This is an internal VA website that is not available to the public.

(2) Ensuring recording in the QA documentation of the examination and in the final report of the examination the radiation dose administered during the procedure using appropriate metrics (e.g., peak skin dose (if available), air kerma and dose area product).

(3) Supervising VA medical facility dependent fluoroscope operators.

(4) If initial didactic training is not performed at the VA medical facility, providing the VA medical facility RSO with evidence of the training topics, dates, duration and successful completion. See paragraph 4 for a full list of training requirements.

v. **VA Medical Facility Dependent Fluoroscope Operator.** VA medical facility dependent fluoroscope operators operate a fluoroscope under the supervision of a VA medical facility independent fluoroscope operator and are appropriately trained in accordance with this directive (e.g., Physician Assistants, Registered Radiologist Assistants (RRAs), Diagnostic Radiologic Technologists, Catheterization Medical Instrument Technicians, Research Assistant Dependent Fluoroscope Operators, or Registered Nurses who perform fluoroscopy). For qualifications of VA medical facility dependent fluoroscope operators, see the mandatory SOP 1105.04-04, Qualifications of Fluoroscope Operators and Levels of Supervision, on NRP's SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.* A dependent fluoroscope operator is responsible for all or part of the following, as delegated and supervised by the VA medical facility independent fluoroscope operator:

(1) Caring for the patient before, during and after fluoroscopic procedures and providing follow-up related to possible fluoroscopically related patient issues. **NOTE:**

See mandatory SOP 1105.04-01, Patient Safety Actions Before, During and After Fluoroscopy and SOP 1105.04-02, Monitoring for Clinical Effects of Fluoroscopic Exposures: Records and Reporting, Patient Counseling and Follow-Up, on NRP's SharePoint site at

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(2) Recording in the QA documentation of the examination the radiation dose administered during the procedure using appropriate metrics (e.g., peak skin dose (if available), air kerma and dose area product).

(3) If initial didactic training is not performed at the VA medical facility, providing the VA medical facility RSO with evidence of the training topics, dates, duration and successful completion. See paragraph 4 for a full list of training requirements.

w. **VA Medical Facility Fluoroscopy Support Staff.** VA medical facility fluoroscopy support staff include staff whose duties affect radiation dose management of the patient (e.g., technologists who select the initial settings of a fluoroscope, technologists who adjust the collimation of the x-ray beam during procedures, and nurses who participate in procedures or perform post-procedure follow-up of patients for possible radiation

effects. Diagnostic Radiologic Technologist students may act as fluoroscopy support staff under appropriate supervision; see VHA Directive 1400.01, Supervision of Physician, Dental, Optometry, Chiropractic and Podiatry Residents, dated November 7, 2019, and VHA Handbook 1400.04(1), Supervision of Associated Health Trainees, dated March 19, 2015). These duties are performed under the direct or personal supervision of a VA medical facility independent fluoroscope operator, except as noted in (2) below (see SOP 1105.04-04, Qualifications of Fluoroscope Operators and Levels of Supervision, on NRP's SharePoint site at:

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

The VA medical facility fluoroscopy support staff may be responsible for all or part of the following, as delegated and supervised by a VA medical facility independent fluoroscope operator:

(1) Supporting set-up of fluoroscopy equipment.

(2) Patient and equipment positioning during a fluoroscopy procedure, including beam collimation, table height and positioning and tube angulation, under the personal supervision of a VA medical facility independent fluoroscope operator.

(3) Monitoring a patient during a fluoroscopy procedure. **NOTE:** See SOP 1105.04-01, Patient Safety Actions Before, During and After Fluoroscopy, on NRP's SharePoint site at

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. This is an internal VA website that is not available to the public.

(4) Performing follow-up after fluoroscopy procedures as requested by the VA medical facility independent fluoroscope operator.

(5) Completing the training listed in paragraph 4 below.

3. HEALTH PROFESSIONS TRAINEES

a. The performance of fluoroscopy is restricted to post-graduate students in clinical disciplines whose scope of practice includes fluoroscopy guided procedures and who are supervised by a VA medical facility independent fluoroscope operator with privileges to perform that procedure.

b. Assignment of HPTs to the performance of fluoroscopic procedures is exclusively at the discretion of the HPTs' PD (either affiliate or VA-based). HPTs assigned to the performance of fluoroscopy procedures must be supervised according to VHA Directive 1400.01 or VHA Handbook 1400.04(1). A VA medical facility independent fluoroscope operator who is privileged to perform the procedure being supervised must be present on-site, and this individual retains ultimate responsibility for patient care.

c. For the HPT who has not reached the level of expertise in fluoroscopy safety as required by the Accreditation Council for Graduate Medical Education (ACGME) PD (or clinical trainee equivalent PD), fluoroscopic procedures must be performed under the

supervision of a VA medical facility independent fluoroscope operator who is physically present in the procedure room when the HPT is performing fluoroscopy.

d. The independent fluoroscopy operator is ultimately responsible for fluoroscopy safety during the procedure. An annual competency assessment (located at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>) must be performed for each HPT performing fluoroscopy. **NOTE:** *This is an internal VA website that is not available to the public.*

4. TRAINING

a. The following initial training is required for persons who operate or supervise the operation of a fluoroscope. This includes VA medical facility independent and dependent fluoroscope operators, including qualified research assistants. The VA medical facility Director is responsible for ensuring that a fluoroscopy safety training program is established in compliance with these requirements (see paragraph 2.k.(4)).

(1) Didactic Training.

(a) Didactic training must include the following topics, with successful completion of a written examination, and occurs as part of credentialing:

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.

(b) The requirement for didactic training may be met by completion of the Talent Management System course: VA 16551: Minimizing Risks from Fluoroscopic X-Rays.

(c) If didactic training was not performed at or by the VA medical facility, the prospective operator must provide evidence of the training topics, dates, duration and successful completion for review and approval by the VA medical facility RSO. **NOTE:** *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. Technologists certified in radiography or radiation therapy from the American Registry of Radiologic Technologists (ARRT), or who are registered*

cardiovascular invasive specialists with Cardiovascular Credentialing International, are considered to have met the didactic portion of the training requirement. RRAs who have obtained certification by ARRT, or non-certified RRAs who otherwise meet the eligibility requirements for the ARRT radiologist assistant certification, and who are given a temporary appointment as a graduate RRA not to exceed 2 years, are also deemed to have met the didactic portion of the training requirement.

(2) **Hands-On Training.** The VA medical facility must have processes to ensure hands-on training is conducted during the FPPE period and prior to first use of the fluoroscope. Training must be conducted on either the same model equipment that is used, or on other equipment of sufficient similarity to enable proficiency in and familiarity with all key functions and features of the equipment that is used, including dose optimization features. The training must encompass the use of controls, activation of various modes of operation and displays.

(3) **Preceptor Training.** Preceptor training and certification consists of operation of the fluoroscope for clinical purposes under the personal supervision of a preceptor VA medical facility independent fluoroscope operator who is experienced in the operation of the device. When feasible, this should be conducted by a practitioner in the same clinical practice (that is, a qualified interventional cardiologist could precept another interventional cardiologist). Completion of this phase of training must occur during the FPPE period in the initial period of use and must include written confirmation, signed by the preceptor, that the individual undergoing initial preceptor training has achieved a level of competency sufficient to function within their scope of practice as an independent or dependent fluoroscope operator as appropriate. Preceptor training is not required for VA medical facility dependent fluoroscope operators who operate only under personal supervision.

b. **Ongoing Training.** Persons who operate or supervise the operation of a fluoroscope must receive refresher training every 2 years. The training must be commensurate with risk to the patient and the staff. It must include the risks from exposure to ionizing radiation, pertinent requirements of this directive, methods for maintaining doses to staff within established limits and ALARA and for protecting the patient. When applicable, hands-on training must be completed when any new equipment is placed in service prior to first use.

c. Safety training is also required for all who work in the room where fluoroscopy is performed. This training must be performed initially and at least every 2 years thereafter. The training must be commensurate with risk to the staff. It must include the risks from exposure to ionizing radiation, pertinent requirements of this directive and methods for maintaining doses to staff within established limits and ALARA.

d. VA medical facility fluoroscopy support staff must receive training, regarding management of radiation dose to the patient or patient follow-up with respect to possible radiation injury, that is appropriate to their duties. This training must be performed initially and at least every 2 years thereafter.

e. **Training for Health Professions Trainees Performing Fluoroscopy.**

(1) HPTs may not be routinely assigned required training beyond the Mandatory Training for Trainees course: VHA Directive 1052, Appropriate and Effective Use of VHA Employee Mandatory and Required Training, dated June 29, 2018.

(2) For HPTs deemed competent to provide fluoroscopy by their PD, no further training is required. See the NRP SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx> for an attestation of competency form for HPTs. **NOTE:** *This is an internal VA website that is not available to the public.*

(3) Affiliate sponsored HPTs deemed not competent to provide fluoroscopy by their PD must complete the fluoroscopy training requirements at a VA academic affiliate. After successful completion, their PD verifies their competency and completes an annual competency verification form for HPTs, located on the NRP SharePoint site at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

5. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1, unless Federal regulations such as those of the Occupational Safety and Health Administration (OSHA) or the Nuclear Regulatory Commission (NRC) require a longer retention period. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

6. BACKGROUND

a. Fluoroscopic imaging is an integral part of health care and is used by many services in a VA 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 large radiation doses to patients, as well as significant radiation doses to the operators and other staff. Patient harm may include stochastic (random) effects, such as cancer related to age at exposure, and tissue reactions (appearing only if a dose threshold is exceeded), related to amount of dose and repetitive exposures, among other factors. 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. OSHA regulates the safety of employees from radiation from machine sources at Federal facilities. See 29 C.F.R. § 1910.1096.

c. When radioactive material is used, and employees receive exposures from the radioactive material in addition to exposure from fluoroscopy (e.g., yttrium-90 microsphere therapies in an interventional suite), the regulations of NRC pertain to the entire radiation exposures. See 10 C.F.R. Parts 19 and 20.

7. DEFINITIONS

a. **As Low As Reasonably Achievable.** ALARA is the principle of maintaining exposures to ionizing radiation as low as is reasonably achievable, with clinical, economic and social factors taken into account.

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

c. **Fluoroscope.** A fluoroscope is a machine which emits x-rays to provide real-time x-ray projection images.

d. **Health Professions Trainee.** An HPT is an individual appointed under 38 U.S.C. §§ 7405 and 7406 who participates in clinical or research training under supervision of their PD to meet program or degree requirements. HPT is a general term to describe a student (undergraduate, graduate, or post-graduate), intern, resident, chief resident, fellow, VA advanced fellow, or pre- or post-doctoral fellow. HPTs can be in a non-clinical, patient care, patient records reviewer, or a data entry training field. ***NOTE: For the purposes of this directive, the term HPT only refers to physician residents.***

e. **Optimization of Dose to the Patient.** For medical exposures of patients, the optimization of dose to the patient is the management of the radiation dose to the patient commensurate with the medical purpose. Optimization is equivalent to keeping dose to the patient ALARA (see paragraph 7.a.).

f. **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.

g. **Research Assistant Dependent Fluoroscope Operator.** A Research Assistant Dependent Fluoroscope Operator is a research team member who operates research fluoroscopy equipment for an approved IRB protocol under the supervision of an independent fluoroscope operator who is part of the research team.

h. **Sentinel Event.** A sentinel event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that results in death, permanent harm or severe temporary harm. A sentinel event pertaining specifically to fluoroscopy is exposure resulting in permanent tissue injury when clinical and technical optimization were not implemented or recognized practice parameters were not followed. ***NOTE: For additional information, see VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.***

i. **Significant Radiation-Related Injury.** A significant radiation-related injury from fluoroscopic exposure is permanent irreversible injury to the skin as evidenced by the following:

(1) **Skin.** Necrosis, ulceration, dermatitis, atrophy or fibrosis, regardless of the need for skin grafting.

(2) **Hair.** Permanent hair loss to the scalp that is cosmetically unacceptable.

j. **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 shielding design and acceptance testing surveys of imaging rooms must conform to NCRP Report No. 147, Structural Shielding Design for Medical X-Ray Imaging Facilities. 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.

k. **Substantial Radiation Dose Level.** An SRDL is a level of radiation dose to a patient that, if exceeded, triggers specific follow-up actions, including notification to 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. SRDL is a peak skin dose of 3 Gy or, if peak skin dose is not available, a cumulative air kerma at the reference point of 5 Gy. **NOTE:** *This definition conforms to Society for Interventional Radiology (SIR) Guidelines and NCRP Report No. 168, Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures:*
<https://ncrponline.org/?s=report+168>.

l. **Supervision.**

(1) **Direct Supervision.** Pursuant to 42 C.F.R. § 410.32, direct supervision is when an independent fluoroscope operator must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of a 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. Although immediate availability of the independent fluoroscopic operator is required, physical presence in the fluoroscopy room during the procedure is not.

(2) **Personal Supervision.** Pursuant to 42 C.F.R. § 410.32, personal supervision is when an independent fluoroscope operator is physically present in the exam or control room while a fluoroscopic procedure 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 if needed for a particular patient. **NOTE:** *For HPTs, this is referred to as "direct supervision". Please see VHA Directive 1400.01 and VHA Handbook 1400.04(1).*

8. REFERENCES

- a. 38 U.S.C. §§ 7301(b), 7405, 7406.
- b. 10 C.F.R. Parts 19 and 20.
- c. 21 C.F.R. § 1020.32.
- d. 29 C.F.R. § 1910.1096.
- e. 38 C.F.R. Part 16.
- f. 42 C.F.R. § 410.32.
- g. 45 C.F.R. Part 46.
- h. VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated, March 24, 2023.
- i. VHA Directive 1052, Appropriate and Effective Use of VHA Employee Mandatory and Required Training, dated June 29, 2018.
- j. VHA Directive 1105, Management of Radioactive Materials, dated February 24, 2021.
- k. VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.
- l. VHA Directive 1400.01, Supervision of Physician, Dental, Optometry, Chiropractic and Podiatry Residents, dated November 7, 2019.
- m. VHA Directive 6300(1), Records Management, dated October 22, 2018.
- n. VHA Handbook 1400.04(1), Supervision of Associated Health Trainees, dated March 19, 2015.
- o. National Health Physics Program X-Ray Imaging Guidance:
<https://dvagov.sharepoint.com/sites/vhanhppmain/SitePages/X-Ray-Imaging-Guidance.aspx>. **NOTE:** This is an internal VA website that is not available to the public.
- p. National Radiology Program SharePoint site:
<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/DocumentLibrary.aspx>. **NOTE:** This is an internal VA website that is not available to the public.
- q. 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.

r. American College of Radiology-American Association of Physicists in Medicine Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures: <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MgmtFluoroProc.pdf>. **NOTE:** *This linked document is outside of VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

s. American College of Radiology-American Association of Physicists in Medicine Technical Quality Assurance in Fluoroscopic Imaging: <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Fluoro-Equip.pdf>. **NOTE:** *This linked document is outside of VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

t. Environmental Protection Agency's Federal Guidance Report No. 14, Radiation Protection Guidance for Diagnostic and Interventional Procedures: <https://www.epa.gov/radiation/federal-guidance-report-no-14-radiation-protection-guidance-diagnostic-and-interventional>. **NOTE:** *This linked document is outside of VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

u. NCRP Report No. 147, Structural Shielding Design for Medical X-Ray Imaging Facilities, 2004: <https://ncrponline.org/?s=report+147>.

v. NCRP Report No. 168, Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures, 2010: <https://ncrponline.org/?s=report+168>.