



VEIN CENTER

IAC Standards for Vein Center Accreditation: Superficial Venous Evaluation and Management – Fluoroscopy

Section 1A: Requirements for Facilities Performing Fluoroscopy

STANDARD – Personnel

1.1A Each facility must have a radiation safety policy that includes training and education for all facility staff that perform or are involved in fluoroscopic procedures.

1.1.1A Fluoroscopic equipment used in superficial venous procedures may only be operated by:

1.1.1.1A A licensed physician with training and experience in fluoroscopic procedures;

OR

1.1.1.2A A registered radiologic technologist [RT(R)].

AND

1.1.1.3A All staff, must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice.

1.1.2A Personnel Required Training and Experience:

1.1.2.1A All individuals in the fluoroscopic procedure room during the procedure must have documentation of a minimum of three hours of documented specific training in radiation safety provided by a medical physicist or qualified expert and received a passing score on a written examination administered by the provider of the radiation safety training program.

1.1.3A Continuing Education (CE) Requirements:

1.1.3.1A A minimum of one hour of CE in radiation protection related to the use of fluoroscopy must be performed yearly and documented.

1.1.3.2A A minimum of three hours of the required CE every three years must be related to radiation safety.

1.1.4A Personnel Responsibilities:

1.1.4.1A Personnel responsibilities may include, but are not limited to:

- i. All personnel in the room during fluoroscopic procedures must wear appropriate radiation protective apparel or have radiation safety equipment (i.e., lead shields, lead barriers) appropriate to the procedure. This includes the patient whenever possible.
- ii. The garment and/or devices must be tested yearly.
- iii. Each person routinely involved in fluoroscopic procedures must also be provided with at least one personnel radiation monitor approved by National Voluntary Laboratory Accreditation Program (NVLAP). Individuals must comply with state regulations regarding monitor placement, dosage monitoring and reporting of dosage exposure.
- iv. Radiation use must be consistent with the “as low as reasonably achievable” principle or ALARA radiation safety guidelines.

- v. Fluoroscopy time or radiation dose data per procedure must be recorded in the patient medical record and be available for review. If radiation dose data are not available or measured, the fluoroscopic exposure time and the number of images acquired must be recorded in the patient's medical record.

STANDARD – Medical Physicist

1.2A A qualified medical physicist must be retained by the facility for the performance of the procedures in Standard 1.2.2A and meet the following qualifications:

1.2.1A Medical Physicist Required Training and Experience:

1.2.1.1A The medical physicist(s) must meet one of the following criteria:

- i. Board certification by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or the Canadian College of Medical Physics (CCMP) in a discipline that includes diagnostic imaging is recommended.
- ii. A physicist who has passed Part 2 of the ABR examination in a discipline of medical physics that includes diagnostic imaging is acceptable. Full certification by a recognized board as outlined above is required prior to the next accreditation cycle.
- iii. Licensed or certified in accordance with state and local regulations. Full certification by a recognized board as outlined above is required prior to the next accreditation cycle. Individuals listed in the National QMP Registry maintained by the Conference of Radiation Control Program Directors for a subspecialty of medical physics in diagnostic imaging are acceptable.

1.2.2A Medical Physicist Responsibilities:

1.2.2.1A The medical physicist(s) responsibilities may include, but are not limited to:

- i. Perform initial and annual surveys (or more frequently as governed by state and local law) for equipment performance evaluation including:
 - radiation output measurements;
 - system quality control tests;
 - image quality performance measurements;
 - analyze all data with appropriate recommendations;
 - appropriate shielding of rooms and areas of the room considered protected from radiation;
 - operation of collimators.
- ii. Provide a written summary of all assessment and evaluations performed.
- iii. Provide guidance for any patient and/or staff dosimetry issues.
- iv. Provide radiation training for facility physicians and staff as required.
- v. Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist in the collection of data under the direct supervision of the medical physicist. **The medical physicist must review and approve all such data. The medical physicist remains personally responsible for the performance quality of the assigned tasks.**

1.2.3A Continuing Education (CE) Requirements:

1.2.3.1A The medical physicist must obtain at least 15 credits hours of CE approved by the Commission on Accreditation of Medical Physics Education Program (CAMPEP) in diagnostic imaging including fluoroscopy, every three years.

- i. The 15 CAMPEP hours should include education in radiation dosimetry, radiation protection and equipment performance related to the use of fluoroscopy.
 - The medical physicist should regularly perform a sufficient number of radiation measurements, dosimetric calculations and equipment performance evaluations of fluoroscopic equipment to maintain competence in the performance of these activities.

Comment: If the medical physicist has successfully attained board certification within the three years prior to the application date, the CE requirement will be considered fulfilled.

- ii. Documentation of CAMPEP credits must be kept on file and available for inspection.

STANDARD – Examination Areas

1.3A In addition to the requirements listed in [Section 2A: Physical Facilities of the complete Vein Center Standards](#), if fluoroscopy is being used, the following requirements apply:

- 1.3.1A the procedure room/area must have radiation shielded barriers that meet state and federal requirements;
- 1.3.2A signage to identify the area as one with active use of x-ray equipment;
- 1.3.3A radiation shielding for patient’s vulnerable organs, if practical with the procedures;
- 1.3.4A there must be restriction of the public to radiation areas.

STANDARD – Equipment and Instrumentation

1.4A In addition to the requirements listed in [Section 2.2A: Equipment and Instrumentation of the complete Vein Center Standards](#), if fluoroscopy is being used, the following requirements apply:

- 1.4.1A A fixed or portable, single or biplane angiography system that must meet the following specifications:
 - 1.4.1.1A digital subtraction imaging of at least two frames per second;
 - 1.4.1.2A high quality, subtracted digital radiographs;
 - 1.4.1.3A last image hold is desirable;
 - 1.4.1.4A pulsed fluoroscopy is desirable;
 - 1.4.1.5A dose measurement capability;

- 1.4.1.6A digital Imaging and Communications in Medicine (DICOM) compatible digital image storage with capability of storing uncompressed images on portable format without loss of image resolution;
 - 1.4.1.7A ability to display and review prior relevant images during the procedure;
 - 1.4.1.8A minimum detector diameter of 9 inches;
 - 1.4.1.9A minimum spatial resolution of matrix of 1000 x 1000;
 - 1.4.1.10A minimum contrast resolution to see the 1.5 mm hole in a standard phantom (see page 4, section 4.b. (low contrast performance) of Guidance Document Fluoro QA Guide posted on intersocietal.org/vein/seeking/sample_documents.htm)
 - 1.4.1.11A image monitor performance using the Society of Motion Picture and Television Engineers (SMPTE) pattern;
 - 1.4.1.12A for equipment installed before 2006 that does not display cumulative dose and or dose area product (DAP), documentation of fluoroscopy time and the number of images per procedure is acceptable.
- 1.4.2A Ancillary equipment as appropriate (e.g., monitoring equipment, blood coagulation testing equipment, workstations, picture archiving communication system (PACS), radiation protection for personnel (aprons and thyroid shields, portable shield either on wheels or suspended from ceiling).

STANDARD – Equipment and Instrumentation Quality Control

- 1.5A There must be a comprehensive Quality Improvement (QI) program to provide a standard of measurement for system performance and the documentation of any variance thereof.
- 1.5.1A Fluoroscopic system QC testing must include a comprehensive evaluation of the system components, image performance, and radiation output limits as outlined in the FDA Code of Federal Regulations (CFR) Title 21 subchapter J, Parts 1010 and 1020 and applicable FDA guidance documents.⁶
 - 1.5.2A Image quality requirements, radiation output limits, and other fluoroscopic performance requirements must also comply with the health-code regulations of the state in which the facility is located.
 - 1.5.3A The qualified medical physicist must complete the performance evaluations at equipment installation and annually, unless state regulations require more frequent testing. Equipment performance evaluations are recommended semiannually to include radiation output measurements, system quality control tests and image quality performance measurements.
 - 1.5.4A The medical physicist must perform a radiation safety survey to ensure that occupational workers and members of the public are shielded according to state regulation. This must be performed prior to installation of each new angiographic imaging system. A documented radiation safety survey of the procedure room and adjacent areas that has been accepted by the State Radiation Program fulfills this requirement.
 - 1.5.5A A radiation safety survey must be performed on all renovated or newly constructed procedure rooms and adjacent areas. This must be performed prior to first patient use. This survey must confirm that the levels of radiation protection are in conformance with the State Radiation Program.

- 1.5.6A All spaces outside the procedure rooms should provide adequate protection for full time occupancy by non-radiation workers. This recommendation includes the control room.
- 1.5.7A Preventive maintenance (PM) service is required per the manufacturers' recommendations or at least annually for each angiographic system at the facility.
- 1.5.8A Ancillary equipment (e.g., monitoring equipment, blood coagulation testing equipment, injectors, workstations, PACS, lead aprons, suction, oxygen lines, etc.) should also be included in a PM program.

STANDARD – Quality Control Documentation

- 1.6A All QC results must be documented and reviewed.
 - 1.6.1A Documentation of the physicists' evaluation, preventative maintenance and quality control tests performed, and service records for all angiographic systems and ancillary equipment must be maintained at the facility and available for review. The reports must be signed and dated by the person(s) performing the tests.
 - 1.6.2A Results of all QC tests must be documented, archived and stored on film, in digital format, or on other suitable media according to state requirements (if applicable).

STANDARD – Contrast

- 1.7A If intravascular contrast media are used, the facility or imaging department must have written policies, protocols, and procedures regarding the administration.
 - 1.7.1A Vascular access must be established or confirmed using the facility's protocol.
 - 1.7.2A Protocols must be in place for treating patients with adverse events.
 - 1.7.3A Reactions and treatment must be documented in the procedure report and/or the patient's medical record in compliance with the operating policies and procedures of the facility.
 - 1.7.4A Emergency equipment and medications listed in [Section 2.2A: Equipment and Instrumentation of the complete Vein Center Standards](#), must be immediately available to treat adverse events related to contrast media administration
 - 1.7.5A Documentation of contrast name and volume administered must be documented in the patients' medical record.
 - 1.7.6A Contrast material as well as any other injectables must be clearly labeled on the procedure table.