INTERSOCIETAL ACCREDITATION COMMISSION

VASCULAR INTERVENTIONAL

IAC Standards for Deep Venous Accreditation

Accreditation Standards

AUGUST 2025

Introduction

The Intersocietal Accreditation Commission (IAC) accredits facilities that provide venous evaluation, management and/or treatment procedures. IAC accreditation is a process by which vein centers can evaluate and demonstrate the level of patient care they provide.

This program is designed to accredit centers that evaluate and manage deep vein disorders to ensure that the center meets benchmarks for quality based on published guidelines, resources, training and outcomes. Medical knowledge for the evaluation and management of deep venous disorders is required.

A deep vein center is defined as a center where venous evaluation and management and/or treatment procedures are performed and is composed of, at a minimum, a qualified Medical Director (MD or DO) and appropriate equipment to perform the procedures. Under the supervision of the qualified Medical Director, there may be additional medical staff (MD or DO), Advanced Practice Providers, ARRT technologists, nurses, ultrasound technologists/sonographers and/or ancillary personnel. All physicians who perform deep venous interventions in the facility must be included in the application for accreditation as part of the medical staff. The center must meet the organizational requirements defined in this document.

Deep Vein: Primary Procedures

The following procedures are available for accreditation:

a. Invasive diagnostic imaging
   i. Venography and/or Intravascular Ultrasound (IVUS)
b. Venous angioplasty and/or stenting for the following indications:
   i. Post-thrombotic obstruction/occlusion of the iliocaval/femoral venous system
   ii. Compressive lesions of the iliac veins (e.g., May-Thurner syndrome)
   iii. Compressive lesions of the renal veins (e.g., Nutcracker syndrome)
   iv. Superior vena cava and central venous stenosis
   v. Treatment of symptomatic in-stent restenosis and stent compression
   vi. Recanalization of occluded stent(s) in symptomatic patients
c. Treatment of pelvic venous reflux with embolization
   i. Internal iliac vein
   ii. Gonadal vein
d. Inferior vena cava filter placement
e. Inferior vena cava filter retrieval/repositioning
f. Invasive treatment of deep venous thrombosis
   i. Catheter directed thrombolysis
   ii. Pharmacomechanical thrombolysis
   iii. Percutaneous mechanical thrombectomy
g. Treatment of venous malformation

New or emerging technologies, protocols and other novel imaging or interventional approaches not included in guidelines published by professional societies must have supporting documentation that demonstrates adherence to manufacturer's training, safety specifications and quality control specifications as applicable. Facilities are encouraged to contact the IAC for guidance related to utilization of new technology not currently addressed in the IAC Standards.

These accreditation Standards represent the minimum requirements to which an accredited deep venous facility is held accountable. These Standards are not intended to be a comprehensive list of requirements to perform a procedure. In addition to all Standards listed below, the facility, including all staff, must comply with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations, and billing requirements.

Standards that are highlighted are changes that were made as part of the August 15, 2025 revision and effective immediately. These changes are minor and were revised for clarification and consistency with existing IAC interventional *Standards* only.

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Part A: Organization

Section 1A: Personnel and Supervision

Note: Facilities performing fluoroscopy may reference additional Standards for Personnel and Supervision in the *IAC Standards for Vascular Interventional Accreditation – Fluoroscopy*.

STANDARD – Medical Director

1.1A The Medical Director must be a licensed physician (MD or DO) in the state or jurisdiction of the vein center.

1.1.1A Medical Director Required Training and Experience:

1.1.1.1A Must be board certified by the American Board of Surgery (ABS), the American Board of Radiology (ABR), the American Board of Internal Medicine (ABIM) or the American Osteopathic Board in one of the following medical specialties:

i. General Surgery
ii. Interventional Cardiology
iii. Interventional Radiology
iv. ABVM Endovascular Examination Diplomat
v. Vascular Surgery

1.1.1.2A Must have performed at least the following number of cases over the previous three years in the areas in which they are applying for accreditation and cases must be documented with a case log (codable procedures may be counted separately even if performed on the same patient in a single setting):

i. Venography – 20 cases
ii. Venous Intravascular Ultrasound (IVUS) – 20 cases
iii. Venous angioplasty and/or stenting (if performed) – 15 cases
iv. Treatment of pelvic venous reflux with embolization (if performed) – 15 cases
v. Inferior vena cava filter placement (if performed) – 15 cases
vi. Inferior vena cava filter retrieval/repositioning (if performed) – 15 cases
vii. Invasive treatment of deep venous thrombosis (if performed) – 15 cases
viii. Treatment of venous malformation (if performed) – 15 cases

1.1.1.3A The Medical Director must have current Advanced Cardiac Life Support (ACLS) certification. If performing procedures on children, medical staff member must follow state regulations (PALS).

1.1.2A Medical Director Continuing Medical Education (CME) Requirements:

1.1.2.1A The Medical Director must obtain a minimum of 30 Category 1 CME credit hours related to venous disease and/or venous interventional treatment in the past three years.

i. At least two hours of fluoroscopy radiation safety training must be obtained as part of the 30 hours of required CME.

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Comment: A facility-based radiation safety program, which provides a minimum of two hours of training every three years will satisfy the radiation safety CME requirement. Documentation of who provided the training, when training occurred, and topics covered must be available for review.

ii. If the Medical Director has successfully completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship in one of the accepted medical specialties within three years prior to the application date, the CME requirement will be waived with the exception of at least two hours of fluoroscopy radiation safety training unless the residency or fellowship explicitly included fluoroscopic radiation safety in its curriculum and there is demonstrative documentation of such.

iii. Documentation of CME credits must be kept on file and available for review.

1.1.3A Medical Director Responsibilities:

1.1.3.1A The Medical Director is responsible for implementing measures to achieve and maintain compliance with the Standards for all services provided, including compliance, radiation safety, outcomes, quality control and quality of care and appropriateness of care provided. The Medical Director responsibilities include but are not limited to:

i. The Medical Director must provide oversight of patient safety and is responsible for a monthly walkthrough with attestation.

ii. The Medical Director (or their designee) must review all updates to all manuals at least annually and as new policies are introduced. This review must be documented, signed and dated on the reviewed document or manual.

iii. The Medical Director must be present at all required Quality Improvement (QI) meetings and must review and sign off on QI documentation. QI documentation must meet the requirements listed in Part C: Quality Improvement.

iv. The Medical Director may supervise the entire operation of the facility or delegate specific operation and is responsible for a monthly walkthrough with attestation and is also responsible for assuring compliance of medical and other staff to the Standards outlined in this document. In addition to adherence to the Standards, the Medical Director must participate in regular QI meetings, case study review conferences, personnel interviews, and other facility operations.

STANDARD – Medical Staff

1.2A The medical staff member must be a licensed physician (MD or DO) in the state or jurisdiction of the vein center.

1.2.1A Medical Staff Required Training and Experience:

1.2.1.1A Must be board certified or board eligible by the American Board of Surgery (ABS), the American Board of Radiology (ABR), the American Board of Internal Medicine (ABIM) or the American Osteopathic Board in one of the following medical specialties:

i. Vascular Surgery

ii. ABVM Endovascular Examination Diplomat

iii. General Surgery

iv. Interventional Radiology

v. Interventional Cardiology

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1.2.1.2A Must have performed at least the following number of cases over the previous three years in the areas in which they are applying for accreditation and cases must be documented with a case log:

i. Venography – 20 cases
ii. Venous Intravascular Ultrasound (IVUS) – 20 cases
iii. Venous angioplasty and/or stenting (if performed) – 15 cases
iv. Treatment of pelvic venous reflux with embolization (if performed) – 15 cases
v. Inferior vena cava filter placement (if performed) – 15 cases
vi. Inferior vena cava filter retrieval/repositioning (if performed) – 15 cases
vii. Invasive treatment of deep venous thrombosis (if performed) – 15 cases
viii. Treatment of venous malformation (if performed) – 15 cases

1.2.1.3A All medical staff must have current Advanced Cardiac Life Support (ACLS) certification. If performing procedures on children, medical staff member must follow state regulations (PALS).

1.2.2A Medical Staff Continuing Medical Education (CME) Requirements:

1.2.2.1A Medical staff must obtain a minimum of 30 Category 1 CME credit hours related to venous disease and/or venous interventional treatment in the past three years.

1.2.2.2A At least two hours of fluoroscopy radiation safety training must be obtained as part of the 30 hours of required CME.

Comment: A facility-based radiation safety program, which provides a minimum of two hours of training every three years will satisfy the radiation safety CME requirement.

1.2.2.3A If the medical staff member has successfully completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship in one of the accepted medical specialties within three years prior to the application date, the CME requirement will be waived with the exception of at least two hours of fluoroscopy radiation safety training unless the residency or fellowship explicitly included fluoroscopic radiation safety in its curriculum and there is demonstrative documentation of such.

1.2.3A Provisional Medical Staff:

1.2.3.1A The qualified Medical Director may appoint a qualified staff member(s) as provisional staff who meets all the above criteria with the exception of the required procedure performance volumes at that institution. Provisional medical staff member must perform a minimum of 5 cases under direct supervision by a qualified medical staff. The Medical Director will be responsible for review of the provisional staff member including biannual review of case log including outcomes. The provisional medical staff member must attain full medical staff status prior to reaccreditation.

1.2.4A Medical Staff Responsibilities:

1.2.4.1A The medical staff is responsible for performing venous evaluation, management and treatment. Responsibilities must include, but are not limited to:

i. Compliance with all the facility's policies, procedures and/or protocols and to the Standards outlined in this document.

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ii. Responsible for equipment training and inspection to ensure safe operating conditions as specified by the manufacturer's guidelines and the Medical Director.

iii. Participation in the facility's comprehensive Quality Improvement (QI) program.

STANDARD – Interventional Technical Staff

1.3A Interventional technologist(s) at the facility must meet the following qualifications:

1.3.1A Interventional Technical Staff Required Training and Experience:

1.3.1.1A Must be a registered radiologic technologist with the American Registry of Radiologic Technologists (ARRT(RT)(R)) or the Canadian Association of Medical Radiation Technologists (CAMRT). ARRT(CV) or ARRT(CI) is recommended.

1.3.1.2A Hands-on training and/or experience in fluoroscopically guided interventions is recommended.

1.3.1.3A Must have current Basic Life Support (BLS) certification.

1.3.2A Interventional Technical Staff Continuing Education (CE) Requirements:

1.3.2.1A Must obtain a minimum of 15 hours of Category I AMA or RCEEM approved CE in the past three years.

1.3.2.2A Fluoroscopy radiation safety training must be part of the CE and not be less than two hours of the 15 hours required.

1.3.2.3A Documentation of CE credits must be kept on file and available for inspection.

Comment: If the interventional technologist staff member has successfully attained an appropriate technical credential within the three years prior to the application date, the CE requirement will be considered fulfilled with the exception of at least two hours of fluoroscopy radiation safety training.

1.3.3A Interventional Technical Staff Responsibilities:

1.3.3.1A The interventional technologist(s) responsibilities may include, but are not limited to:

i. reporting to the Medical Director or medical staff;

ii. positioning of the patient, selection of radiation exposure parameters, imaging of the patient and archiving of the images;

iii. maintaining a high degree of awareness of all radiation and patient safety issues involved with any invasive procedure;

iv. demonstrating a thorough understanding and working knowledge of normal and abnormal anatomy, physiology, radiation safety, interventional supplies and equipment operation;

v. recognizing and resolving equipment problems and discrepancies, anticipating patient needs and concerns and communicating the appropriate care needed;

vi. scrubbing in and assisting the physician in the procedure when necessary;

vii. circulating within the procedure room and procuring equipment needed for any given procedure; and

viii. performing other duties, as assigned.

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STANDARD – Advanced Practice Provider (APP)

1.4A The Advanced Practice Provider (APP) works under the direction of the Medical Director or a medical staff member who is listed in the application. The APP must be a licensed professional who possesses knowledge in the treatment of venous disorders and meets the required certification and experience qualifications as outlined in this document and the required certification and experience qualifications determined by local, state and/or federal regulations within the scope of practice of an APP.

1.4.1A APP Required Training and Experience:

1.4.1.1A The APP must meet one of the following criteria for required certification:

i. Physician Assistant (PA)
ii. Nurse Practitioner (NP)

1.4.1.2A The APP must have current Basic Life Support (BLS) certification, and if performing procedures with moderate/IV sedation, Advanced Cardiac Life Support (ACLS) certification is required.

1.4.1.3A The APP must perform, under the direct supervision a qualified physician, evaluation of a minimum of 50 venous patients in the previous three years including obtaining a history, performing a physical examination and making medical decisions including the assessment of pertinent diagnostic studies and forming a treatment plan. The qualified physician must be present in the office suite; immediately available.

1.4.2A APP Continuing Medical Education (CME) Requirements:

1.4.2.1A The APP must obtain a minimum of 30 Category I CME credit hours or dedicated CME for APP related to venous disease and venous interventional treatment, in the past three years.

1.4.2.2A At least two hours of CME must be dedicated to fluoroscopy radiation safety.

1.4.2.3A Documentation of CME credits must be kept on file and available for inspection.

1.4.3A APP Responsibilities:

1.4.3.1A APP responsibilities may include, but are not limited to:

i. participation in deep venous interventional procedure safety practices including, but not limited to, safe use of equipment and review of patient outcomes and complications;
ii. administering and monitoring moderate sedation;
iii. monitoring and assessing clinical status of patient;
iv. cardiovascular and hemodynamic monitoring and management;
v. monitoring, assessing and management of emergency care;
vi. advising patient care team and treating patient appropriately;
vii. post-procedure discharge instructions;
viii. patient education;
ix. demonstrating familiarity and proficiency with the setup and operation of all equipment associated with deep venous procedures performed in the facility;
x. may assist with procedures under personal supervision of a qualified medical staff member; and
xi. performing other duties, as assigned.

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1.4.4A Provisional APP:

1.4.4.1A The qualified Medical Director may appoint a qualified APP as provisional staff who meets all of the above criteria with the exception of the required patient evaluation volumes. The Medical Director will be responsible for review of the provisional APP including biannual review of the case log including outcomes. The provisional APP must attain full APP status prior to reaccreditation.

STANDARD – Nursing Staff

1.5A A nurse works under the direction of the Medical Director or a medical staff member who is listed in the application. The nurse must be a licensed registered nurse (RN) or licensed practical/vocational nurse (LPN/LVN) who possesses knowledge in the treatment of venous disorders and meets the required certification and experience qualifications as outlined in this document.

1.5.1A Nursing Staff Required Training and Experience:

1.5.1.1A The nursing staff must have current Basic Life Support (BLS) certification, and if performing procedures with moderate/IV sedation, Advanced Cardiac Life Support (ACLS) certification is required.

1.5.2A Nursing Staff Continuing Education (CE) Requirements:

1.5.2.1A The nurse must obtain a minimum of 30 contact hours/Category 1 CME related to venous disease in the past three years. All CE hours must be approved (i.e., AMA Category I, Society of Vascular Ultrasound (SVU), Society of Diagnostic Medical Sonography (SDMS), American Nurses Credentialing Center (ANCC-Category I), Society for Vascular Nursing (SVN)).

1.5.2.2A At least two hours of CE/CME each cycle must be dedicated to fluoroscopy radiation safety.

1.5.2.3A The CE/CME requirement will be waived (with the exception of at least two hours of radiation safety training) if, in the previous three years, the nurse has:

i. completed formal training;
ii. acquired an appropriate vascular credential (Registered Vascular Technologist (RVT), Registered Vascular Specialist (RVS), Registered Technologist Vascular Sonography [RT(VS)], Registered Phlebology Sonographer (RPhS)); and
iii. has been employed in the facility less than a year.

1.5.2.4A Documentation of CE/CME credits must be kept on file and available for inspection.

1.5.3A Nursing Staff Responsibilities:

1.5.3.1A Nursing staff responsibilities may include, but are not limited to:

i. administering and monitoring moderate sedation;
ii. performing cardiovascular assessment;
iii. monitoring and assessing clinical status of patient;
iv. cardiovascular and hemodynamic monitoring and management;
v. advising patient care team and treating patient appropriately;
vi. demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the deep venous procedures performed in the facility; and

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vii. may assist with procedures under personal supervision of a qualified medical staff member.

STANDARD – Ancillary Personnel

1.6A The facility must ensure that adequately trained and experienced ancillary personnel are available to perform safe and effective patient care appropriate for the level of service as designated by the Medical Director or a qualified designee. The specific needs of a facility must be determined by an evaluation of the types and volumes of procedures as well as facility configuration.

1.6.1A Ancillary personnel may consist of, but are not limited to:

1.6.1.1A advance practice nurses (APRN);

1.6.1.2A certified registered nurse anesthetist (CRNA);

1.6.1.3A radiologist assistant (RA);

1.6.1.4A clinical pharmacist;

1.6.1.5A technical assistants;

1.6.1.6A clerical and administrative assistants;

1.6.1.7A computer support staff; or

1.6.1.8A equipment support staff (i.e., biomedical, x-ray service).

1.6.2A All ancillary personnel within the department must be supervised by the Medical Director or a qualified designee. The supervisor must document/verify proper training at least annually and current competence of their ancillary personnel appropriate to the assigned duties.

STANDARD – Medical Physicist

1.7A A qualified medical physicist must be retained by the facility, assume the responsibilities as outlined in Standard 1.7.2A, and meet the following qualifications.

1.7.1A Medical Physicist Required Training and Experience:

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

1.7.1.1A Board certification by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or the Canadian College of Physicists (CCPM) in diagnostic medical physics or equivalent.

1.7.1.2A Passed Part 2 of the ABR examination and completed a CAMPEP-approved residency in a medical physics discipline, including diagnostic imaging, is acceptable. As outlined above, a recognized board certification is required prior to the next accreditation cycle.

1.7.1.3A If necessary for each state, the medical physicist must be licensed or certified as a diagnostic medical physicist.

1.7.2A Medical Physicist Responsibilities:

1.7.2.1A The medical physicist(s) responsibilities may include, but are not limited to:

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1.7.2.2A The medical physicist should regularly perform radiation measurements, dosimetric calculations, and equipment performance evaluations of fluoroscopic equipment to maintain competence in performing these activities.

1.7.2.3A The physicist should observe at least one fluoroscopically guided procedure within each accreditation modality/area annually.

i. Acceptance (initial) tests and annual surveys (or more frequently as governed by state and local regulations) for equipment performance evaluation, including:

- maximum and typical radiation output measurements in at least one clinically used protocol with a common set of operator-controlled parameters (i.e., pulse rate, field-of-view, etc.);
- accuracy assessment of all fluoroscope reported or displayed radiation dose indices;
- system quality control tests ensuring proper functionality and operation of the fluoroscope for safe and effective operation; and
- assessment of image quality in at least one clinically used fluoroscopy mode setting and one clinically used acquisition mode setting.

ii. Where necessary, evaluation of the radiation shielding adequacy and integrity ensuring necessary radiation protection to individuals in all adjacent areas (only necessary at the initial survey, after any modifications to the structural shielding or replacement of the imaging equipment).

iii. Assessment of proper functioning of collimators and tissue compensation filters.

1.7.2.4A The medical physicist must provide a written summary report to the Medical Director or Radiation Safety Officer and include in the summary report any identified issues requiring corrective action or recommendations for improvement.

1.7.2.5A Provide written guidance for any patient or staff dosimetry issues.

1.7.2.6A Provide radiation training for personnel as required.

1.7.2.7A Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist in the data collection under the direct supervision of the medical physicist (i.e., the physicist must be on premises and immediately available). The medical physicist must review and approve all such data. The medical physicist remains personally responsible for tasks.

1.7.3A Continuing Education (CE) Requirements:

1.7.3.1A The medical physicist must obtain at least 15 credit hours of CE approved by the Commission on Accreditation of Medical Physics Education Program (CAMPEP) in diagnostic imaging every three years; at least three credits of which must be directly related to fluoroscopy.

Comment: Actively participating and fulfilling the requirements of ABR MOC meets this requirement.

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.

1.7.3.2A Documentation of CE credits must be kept on file and available for inspection.

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Section 2A: Facility

Note: Facilities performing fluoroscopy may reference additional Standards for Facility in the *IAC Standards for Vascular Interventional Accreditation – Fluoroscopy*.

STANDARD – General Facility Standards

2.1A Facilities must comply with all federal, state and local regulations.

2.1.1A Adequate space must be provided for all facility operations to ensure patient comfort, safety, dignity, and privacy, as well as staff comfort and safety. Procedure areas must have sufficient space, be well-maintained, and be clean. There should be adequate space for personnel to access the patient and maintain the sterile field.

2.1.2A There must be adequate space for performing resuscitation in case of an emergency. This includes facility configuration and doorways for the emergency transport of patients from patient care areas and emergency exit of staff.

STANDARD – Areas (Physical Facility)

2.2A Area requirements include, but are not limited to:

2.2.1A General Areas

2.2.1.1A waiting, reception and patient/staff bathrooms;

2.2.1.2A patient education, consultation and examination areas; and

2.2.1.3A readily accessible hand washing/sanitation stations for staff.

2.2.2A Procedure Areas

2.2.2.1A pre-test/post-procedure areas within proximity of the procedure area;

2.2.2.2A substerile scrub area;

2.2.2.3A substerile entrance(s) must have:

i. dedicated or shared entrance between adjacent procedure rooms;
ii. entrance for patient transport from the prep area to the laboratory(s); and
iii. egress that connects to hallways leading to other clinical areas.

2.2.2.4A dedicated control room/area(s) must have:

i. leaded wall with a large leaded viewing window if the procedure room is contiguous with the control room;
ii. two-way intercom system; and
iii. desk space adequate to accommodate fluoroscopy monitors, hemodynamic /physiologic recording systems, etc.

2.2.2.5A procedure room/area(s) must have, but is not limited to the following:

i. positive airflow when a device is implanted, there is a skin incision, or prolonged procedure more than two hours;

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ii. high flow oxygen and vacuum for suctioning;

iii. medical gas availability:

- When general anesthesia is used, the following must be available in the procedure room:
  - nitrous oxide; and
  - waste gas lines.

iv. Room Utilities: Adequate utilities based on the types of procedures and workload. These utilities include water taps, lighting, electrical outlets, emergency power, telephones, heating/cooling and ventilation.

v. General Room Lighting: Overhead and task lighting must be adequate to perform procedures, clinical evaluation and patient treatment. The overhead lighting must be able to be dimmed during fluoroscopy. It is recommended that the overhead lighting be controlled by a foot pedal used by the operating physician.

- Additionally, the procedure room must have surgical lighting for any procedure requiring access, device implantation, or that may require a surgical intervention.

vi. Room Power: The facility must have a plan that outlines the response to unexpected power loss or computer function, such as moving the patient to another procedure room in the immediate vicinity.

- When normal power is unavailable, emergency power should provide a minimum of 10 minutes of fluoroscopy and at least one hour of backup power for the computers, monitoring equipment and ancillary equipment.
- There should be sufficient emergency power supply to run fluoroscopy equipment for 10 minutes and run the remainder of the x-ray system components, including lighting, for at least 24 hours.
- The utilization of emergency power must be visible to the operator in the normal working position.
- An uninterruptible power supply for all computer equipment is required.
- X-ray equipment and computers should not require rebooting during the transition between normal and emergency power or during power line instabilities.

2.2.2.6A Interpretation/Dictation Areas

i. Adequately designed space must be provided to interpret examination results and prepare reports.

2.2.2.7A Storage Areas

i. Storage areas must ensure confidentiality of data and should be safe from fire, flood, power outage and natural disasters.

ii. Adequate space must be provided for:

- patient records, reports and digital data storage areas;
- administration records and support areas; and
- equipment/supply storage areas.

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STANDARD – Equipment, Instrumentation and Supplies (Non-Fluoroscopy)

2.3A Equipment Type

2.3.1A Procedure-Specific Equipment – All facilities must have procedure-specific equipment (e.g., ablation systems, implantation devices, lead extraction, etc.) appropriate for the types and volume of procedures performed, including pediatric equipment and supplies, if applicable.

2.3.2A Monitoring Equipment – All facilities must have routine monitoring equipment (e.g., ECG, blood pressure, pulse oximetry, etc.) appropriate for the types and volume of procedures performed, including pediatric equipment, if applicable.

2.3.3A Ancillary Equipment – Ancillary equipment (e.g., transesophageal echocardiography, ultrasound imaging, etc.) appropriate for the types and volume of procedures performed, including pediatric equipment, if applicable, must be available as appropriate.

2.3.4A Supplies – Adequate disposable supplies must be immediately available (e.g., catheters, wires, stents, balloons and embolic protection devices, sheaths, snares, intravenous fluids, needles, and syringes) appropriate for the types and volume of procedures performed, including pediatric equipment, if applicable, must be available as appropriate.

2.3.5A Medications – Pharmacologic agents (i.e., IV fluids, local anesthetics, analgesics, anxiolytics, medications to treat allergic or anaphylactic reactions, anticoagulation medications or reversal agents, sclerosants, embolizing agents) appropriate for the types and volume of procedures performed, including pediatric doses, if applicable, must be readily available for use during the procedure.

2.3.5.1A If sedation or anesthesia is administered refer to Standard 4.5A and also Standard 4.2A regarding medication safety.

2.4A Equipment, Instrumentation and Supplies Quality Control

2.4.1A There must be a comprehensive Quality Assurance (QA) program to provide a standard of measurement for system performance and the documentation of any variance thereof.

2.4.2A Equipment and instrumentation must be appropriate, in good working condition, and routinely inspected for safety and proper functionality per local, state, and/or federal regulations.

2.4.3A Preventive maintenance (PM) on all equipment is required according to the manufacturer's recommendations.

2.4.4A There must be a process to regularly check inventory of disposable supplies (e.g., catheters, wires, balloons, stents, embolic protection devices, contrast) and medications to ensure they are not expired and are readily available during a procedure.

2.5A Quality Control Documentation

2.5.1A All equipment preventive maintenance, service, and quality control results must be documented and reviewed. The records must be signed and dated by the person(s) performing the tests.

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Section 3A: Safety

Note: Facilities performing fluoroscopy may reference additional Standards for Safety in the *IAC Standards for Vascular Interventional Accreditation – Fluoroscopy*.

STANDARD – Patient and Staff Safety

3.1A All safety policies must adhere to state and federal regulations.

3.1.1A Safety policies must be consistently followed. Policy reviews must be documented annually.

3.1.2A There must be written policies and procedures for:

3.1.2.1A Patient Identification – Patients must be accurately identified using two independent patient-specific identifiers before procedure initiation.

3.1.2.2A Informed Consent – Informed consent must be obtained and documented in the patient's medical record consistent with the rules and regulations required by the hospital or facility.

3.1.2.3A Surgical/Procedural Time-Out – The facility must accurately identify and document the correct patient, site, and planned procedure before initiating procedure and sedation. The proper patient name or identification must also be on the imaging system.

3.1.2.4A Fire Safety Evaluation – A fire safety evaluation must be performed immediately before procedure initiation whenever there is potential for a flammable substance to be used in the presence of oxygen.

3.1.2.5A Infection/OHSA/Universal Precautions – All staff must adhere to universal precautions and infection control measures consistent with CDC and OSHA guidelines.

3.1.2.6A Incident Report/Adverse Events – The facility must have a process to document adverse events (i.e., contrast reactions, patient falls, emergencies).

3.2A Medication Safety

3.2.1A All medications, including sclerosants, embolizing agents, contrast, anesthetic agents, and pre-mixed pharmacologic agents, must be labeled with the medication and concentration. This includes all containers such as syringes, medicine cups, IV bags, and basins. The expiration date must also be verified.

3.2.2A Multiuse vials must be marked with the drug name, concentration, date of creation, initials of who made it, and expiration date.

3.2.2.1A A new needle and syringe must be used for every entry into the vial.

3.2.2.2A The vial stopper must be disinfected with an alcohol swab or equivalent antiseptic prior to entry.

3.2.2.3A To avoid contamination, venting needles or other objects may not be left in the stopper.

3.3A Emergency Equipment

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3.3.1A All local, state, and federal regulations for emergency medical care must be followed. In the absence of such regulations, current American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care must be followed.

3.3.2A There must be at least one Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS) certified staff member on-site and immediately available as long as patients are treated in the facility.

3.3.3A All facilities must have a medical emergency response plan, equipment, medications, and supplies appropriate for the types and volume of procedures performed, including pediatric equipment and supplies, if applicable.

3.3.4A The emergency response cart (crash cart) or kit must be immediately available and an appropriate number for the volume of procedures performed. The emergency response cart must include, at a minimum, the following:

3.3.4.1A defibrillator/automated external defibrillator (AED) with appropriate pad size available along with a backup defibrillator;

3.3.4.2A oxygen tanks or wall-mounted oxygen sources with appropriate-sized airways, cannulae and masks;

3.3.4.3A emergency medications in compliance with current ACLS or PALs guidelines;

3.3.4.4A intubation, suction equipment and supplies according to the American Society of Anesthesiology (ASA) Guidelines;

3.3.4.5A equipment and supplies for starting and maintaining intravenous access according to the American Society of Anesthesiology (ASA) Guidelines;

3.3.4.6A The emergency response cart or kit must be checked at least monthly, with documentation to ensure all expected items are present and that supplies/medications are not expired.

3.3.5A All emergency equipment must be clearly labeled and be for emergency use only.

3.3.6A Emergency equipment and medications must be secured with a disposable plastic lock.

3.4A Anesthesia

3.4.1A If sedation or anesthesia is administered, the facility must have written policies regarding their use that are in accordance with local/state guidelines and anesthesia guidelines. In the absence of such guidelines, the American Society of Anesthesiologists (ASA) Guidelines must be followed.

3.4.2A If moderate sedation is administered, physician/advanced practice provider certification must be documented.

3.4.3A At least one person in the procedure room must have Advanced Cardiac Life Support (ACLS) certification or Pediatric Advanced Life Support (PALS) certification for pediatric patient populations.

3.4.4A During sedation and anesthesia, there must be methods to assess the patient's level of consciousness pre-procedure and throughout the procedure.

3.4.5A At a minimum, the following monitoring equipment must be available with documentation if utilized:

3.4.5.1A non-invasive blood pressure;

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3.4.5.2A pulse oximetry;

3.4.5.3A ECG monitoring; and

3.4.5.4A capnography (CO2) monitoring, if applicable.

3.4.6A Sedation and anesthetic agents must be clearly labeled with content, concentration and expiration date.

3.4.7A The type and level of sedation/anesthesia (e.g., moderate, deep, general anesthesia) must be documented in the patient's medical record.

3.5A Sterilization of Medical Instruments

3.5.1A The reuse of an FDA-approved single use device is not permitted unless it is done in compliance with FDA requirements.

3.5.2A Single and multiple-use products must be used before the expiration date.

3.5.3A Products approved by the FDA for multiple uses must be re-sterilized by a process approved by the FDA or Center for Disease Control (CDC), as applicable.

3.5.4A If sterilization is performed on-site, the facility must have a written policy. The policy must include, but is not limited to:

3.5.4.1A comprehensive training requirements for all staff assigned;

3.5.4.2A reprocessing instructions (provided by the instrument/sterilization manufacturer);

3.5.4.3A sterilizer maintenance as needed with records of service;

3.5.4.4A description of quality control tests per manufacturer's recommendation and documentation thereof;

3.5.4.5A instructions for process monitoring and reporting;

3.5.4.6A instructions for visual inspection of packaging materials including heat-sensitive indicators inside each package treated with steam sterilization;

3.5.4.7A results of periodic biological monitoring performed at least weekly;

3.5.4.8A retainment of sterilization records for a period that complies with the CDC standards (e.g., three years), statutes of limitations and state and federal regulations; and

3.5.4.9A an established blood-borne pathogen exposure control plan must be in accordance with OSHA Blood-borne Pathogens Standards, and universal precautions must be used.

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Section 4A: Administrative

STANDARD – Patient Confidentiality

4.1A All facility personnel must ascribe to professional principles of patient-physician confidentiality as required by federal, state, local or institutional policy or regulation.

STANDARD – Patient or Other Customer Complaints

4.2A There must be a policy in place outlining the process for patients or other customers to issue a complaint/grievance in reference to the care/services they received at the facility and how the facility handles complaints/grievances.

STANDARD – Primary Source Verification

4.3A There must be a policy in place identifying how the facility verifies the medical education, training, appropriate licenses and certifications of all physicians as well as the licensing, certification and training of all staff members and any other direct patient care providers.

STANDARD – Record Retention

4.4A All medical records, including archived images, must be retained in accordance with applicable state or federal guidelines for medical records, generally five to seven years.

STANDARD – Information Security

4.5A Information technology security must be maintained according to state and federal regulations.

Comment: Sample documents are available for each of the required policies listed in Section 5A on the IAC website at intersocietal.org/helpful-resources/sample-documents-repository.

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Part B: Process

Section 1B: Procedures

STANDARD – Procedure Overview

1.1B These Standards include the minimum requirements for the performance of deep venous procedures. The Standards are not intended to be a comprehensive list of requirements to perform a case, nor does it list every step necessary for every patient. It represents an overview of the general steps to perform a typical elective case in order to provide a context for the overall requirements of this accreditation program. A facility may find it helpful to use this description to create an institutional template to be used as a reference when analyzing outcomes.

1.1.1B The facility must assure that appropriate staff members with BLS or ACLS, or PALS certification are present during the procedure.

1.1.2B Appropriate staff must be available to assist the patient should an adverse event occur during the procedure and/or recovery.

1.1.3B All staff must adhere to:

1.1.3.1B standardized uniformly applied universal precautions in every aspect of patient care;

1.1.3.2B national patient safety goals (e.g., medication safety);

1.1.3.3B infection control measures consistent with CDC and OSHA guidelines;

1.1.3.4B When in the presence of ionizing radiation, all staff must observe proper radiation safety techniques to include, but not limited to:

i. wearing radiation protective garments; thyroid shield, vest with skirt or full-length apron or full-length jacket. Garments must meet a lead equivalent of 0.5mm with a weight per unit area of 7 kg/m2.

1.1.3.5B Alternatively, staff may use a floor-mounted/portable radiation protection cabin and a ceiling- or gantry-mounted suspended radiation protection system. However, all staff using these systems must be able to completely fit behind these lead barriers whenever radiation is being used.

STANDARD – Procedure Requirements

1.2B FDA-approved devices must be used when feasible.

1.3B Appropriate surgical instruments, equipment and medical supplies, as defined by the procedure, including but not limited to:

1.3.1B fluoroscopic equipment with digital subtraction capability;

1.3.2B appropriate radiation protection for patient and provider;

1.3.3B pharmacologic and anesthetic agents and supplies:

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1.3.3.1B premixed pharmacologic and/or anesthetic agents must be clearly labeled with content, concentration and expiration date.

1.3.4B appropriate monitoring equipment;

1.3.5B appropriate supplies for performance of the procedure;

1.3.6B adherence to published guidelines for the performance of all procedures;

1.3.7B ultrasound imaging as defined by the procedure;

1.3.8B review of preoperative history and imaging;

1.3.9B appropriate baseline labs, as indicated;

1.3.10B reconciliation of medications;

1.3.11B sterile prep and drape; and

1.3.12B appropriate sedation monitoring, based on ASA guidelines.

STANDARD – Documentation

1.4B Pre-Treatment Documentation

1.4.1B A clinical evaluation of each patient being considered for treatment must be performed and documented in their medical record and must include, but is not limited to:

1.4.1.1B chief complaint(s);

1.4.1.2B complete history that includes:

i. a review of past medical history:
- medications;
- allergies; and
- number of pregnancies and live births.

ii. venous history;
iii. family history of venous disease;
iv. history of previous VTE;
v. venous symptoms and treatment history;
vi. include anticoagulation medication and treatment length; and
vii. a directed physical examination that includes a cardiac and pulmonary examination.

Comment: Any changes in medical history, medications, allergies must be documented with each encounter.

1.4.1.3B clinical class (CEAP) and revised Venous Clinical Severity Score (VCSS) at baseline for the affected limb or limbs, repeat at designated follow-up;

1.4.1.4B disease-specific measures such as CIVIQ, VEINes, AVVQ, VVSymQ, and SVP are encouraged;

1.4.1.5B additional imaging and/or consultations;

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1.4.1.6B indication for procedure and treatment plan;

1.4.1.7B Laboratory studies, when clinically indicated, must be completed within 30 days of procedure and must be documented in the medical record to include, but not limited to:

i. electrolytes;
ii. blood urea nitrogen (BUN);
iii. creatinine;
iv. complete blood count (CBC);
v. blood type and screen (if indicated);
vi. Prothrombin time (PT) (INR), if taking warfarin;
vii. pregnancy test performed within 24 hours of procedure (in all females of childbearing age);
viii. AntiXA level (when appropriate); and
ix. additional procedure specific documentation as required.

1.5B Pre-Procedure Documentation:

1.5.1B Must be documented in the medical record:

1.5.1.1B signed and dated complete procedure-specific informed consent;

1.5.1.2B name of treating physician and patient;

1.5.1.3B list of patient allergies (if any);

Comment: No known allergies must also be documented.

1.5.1.4B Mallampati score, when patient is being sedated;

1.5.1.5B ASA score, when patient is being sedated; and

1.5.1.6B additional procedure-specific documentation as required.

1.6B Intra-Procedure Documentation:

1.6.1B Procedural time out:

1.6.1.1B Assessment and documentation of the correct patient, verification of allergies, correct site and procedure must occur immediately before initiation of the procedure.

1.6.2B Vital signs must be documented at least every 10 minutes or when significant physiologic changes occur (when indicated and when/or moderate sedation is use):

1.6.2.1B blood pressure;

1.6.2.2B continuous pulse oximetry;

1.6.2.3B pain scale assessment (if patient is able to report);

1.6.2.4B patient level of consciousness;

1.6.2.5B continuous EKG tracing; and

1.6.2.6B respiratory rate.

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1.7B Procedure Documentation:

1.7.1B Must be documented in the medical record.

1.7.1.1B Operative report (or nursing record, if relevant) must include:

i. indications for the procedure;
ii. detailed description of the procedure;
iii. structures imaged;
iv. operative findings;
v. treatment performed with success/inadequacy;
vi. all complications of intervention;
vii. diagram of the vessel or area treated may be included;
viii. sedation/monitoring provider, number of minutes of sedation and agents(s) used;
ix. documentation of sterile skin preparation and drape;
x. devices used;
xi. access site, technique (ultrasound-guided), access needle and sheath;
xii. all medications administered pre and intraprocedural including but not limited to:
- sedation (total time, type and dose);
- sclerosant dose and type; and
- anticoagulants/antithrombotics.

xiii. fluoroscopy exposure:
- fluoroscopy time; and
- radiation dose indices.

xiv. treated vessel(s):
- length (if applicable); and
- energy deposited (if applicable).

xv. estimated blood loss;
xvi. contrast type and volume;
xvii. patient status at end of procedure;
xviii. name of person performing procedure; and
xix. surgical assistant and/or circulator.

1.7.2B Additional information to be documented in the procedural medical record:

1.7.2.1B additional procedure-specific documentation as required;

1.7.2.2B procedure start and end time;

1.7.2.3B anticoagulation; and

1.7.2.4B additional medications administered intraoperatively.

1.8B Patient Instructions:

1.8.1B Must be documented in the medical record and include:

1.8.1.1B procedure performed;

1.8.1.2B management of post-procedure pain;

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1.8.1.3B anticoagulation or antiplatelet therapy and monitoring instructions;

1.8.1.4B access site, dressings and wound care;

1.8.1.5B compression instructions (if needed);

1.8.1.6B bathing/showering instructions;

1.8.1.7B patient activity, ambulation and exercise;

1.8.1.8B air and car travel restrictions;

1.8.1.9B possible adverse events or complications which may require contact with a health care provider;

1.8.1.10B directions and contact information to access the health care team;

1.8.1.11B follow-up office visit instructions; and

1.8.1.12B follow-up duplex ultrasound examination appointment, if appropriate.

STANDARD – Required Protocols and Policies

1.9B There must be a written protocol for each procedure performed in the facility with indications, contraindications, pretreatment evaluation and reporting outcomes including, but not limited to:

1.9.1B treatment of allergic reactions or toxicity that results from the use of any administered medications during the procedure and/or during recovery ensuring patient safety, including supplies to be used, staff to be present and medications for administration;

1.9.2B intravenous fluid and medication(s) to include access and management;

1.9.3B contrast use and protection protocols; and

1.9.4B monitoring patients undergoing procedures using sedation and anxiolysis.

1.10B There must be written policies for:

1.10.1B Patient Pregnancy Policy – For all clinical procedures there must be a process that assures that patients who could be pregnant are identified. This must be documented and contain the signature/initials of the patient and a member of the medical team, verifying the information. This procedure must include an explanation of the proper steps to be taken if a patient may be or is pregnant, explanation of shielding and recording of estimated fetal radiation dose of procedure is performed.

1.10.2B Patient Pre-Procedure Preparation Policy – There must be a policy in place for determining and administering any necessary pre-test preparations including:

1.10.2.1B education/instructions such as dietary or medication restrictions, examination specific preparation or other relevant information;

1.10.2.2B sufficient time must be allowed for adequate patient preparation; and

1.10.2.3B any other types of necessary pre-test preparation must be assessed prior to the start of the examination.

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1.10.3B Contrast/Medication Administration and Supervision Policy – This policy must address the following, but is not limited to:

1.10.3.1B the steps taken to identify patients with documented or possible sensitivity to contrast and/or at increased risk for renal toxicity and protocols in place to treat these patients.

1.10.3.2B medication and contrast administration procedures and the oversight of the contrast/medication administration and must include, but is not limited to:

i. IV access including location of insertion site and size of catheter;
ii. medications, including contrast, used in the procedure (i.e., beta blockers, conscious sedation);
iii. dosage, timing, route of administration;
iv. patient instruction;
v. patient monitoring;
vi. any precautions or restrictions needed; and
vii. treatment of adverse reactions.

1.10.4B Protocol for patients requiring escalation of care:

1.10.4.1B must have transfer agreement with a hospital;

1.10.4.2B must have a protocol in place for transport to a higher level of care;

1.10.4.3B must include appropriate documentation for transfer of information to the receiving facility; and

1.10.4.4B must maintain a log of all patients requiring escalation of care and their outcomes following state mandates for review and reporting.

1.10.5B Patient radiation dose evaluation:

1.10.5.1B must have a policy which identifies patient radiation dose indices that trigger patient education and follow-up for a potential radiogenic tissue reaction; and

1.10.5.2B must have a summary of patients/procedures exceeding the identified level. Summary must be reviewed monthly by the Medical Director and/or the radiation safety committee.

1.10.6B Patient post-procedure follow-up policy:

1.10.6.1B At a minimum, the facility must contact the patient the next business day following the procedure to follow up on patients' condition and ensure no complications.

1.10.6.2B Patient must be seen within six weeks post-procedure in person or by televisit to ensure efficacy and no complications.

1.10.6.3B Must be documented in the medical record.

1.10.6.4B Follow-up must occur at an appropriate interval of time:

i. Treatment of pelvic venous reflux with embolization
   - At least six months until patient is stable.
ii. Invasive treatment of deep venous thrombosis

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- Initial post-op visit within six weeks and ensure patient has anticoagulation monitored and return as needed.

iii. Treatment of Venous Malformation

- At least six months until patient is stable for one year. If further follow-up is required, and the patient is currently not enrolled in a vascular malformation clinic, consider referral.

iv. Inferior vena cava filter placement

- Initial post-op visit within four weeks.
- For retrievable filters, continued follow-up until patient is deemed to be a candidate for retrieval or if filter is deemed permanent.
- A log should be maintained for all patients and data when filters are not removed by the standard set.

v. Inferior vena cava retrieval/repositioning

- Initial post-op visit within four weeks.
- For retrievable filters, continued follow-up until patient is deemed to be a candidate for retrieval or if filter is deemed permanent.

vi. Venous angioplasty and/or stenting

- Initial post-op visit within four weeks with imaging (as clinically appropriate) then continued follow-up at least every 6-12 months while intervention is patent.
- Recommend serial assessment with venous QoL tool.

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Part C: Quality Improvement

Section 1C: Quality Improvement Program

STANDARD – QI Program

1.1C The facility must have a written Quality Improvement (QI) program to evaluate all types of procedures performed in the facility on an ongoing basis. The QI program must include the QI measures outlined below but may not be limited to the evaluation and review of:

1.1.1C procedure/test appropriateness;

1.1.2C technical quality and performance of the procedure;

1.1.3C patient safety;

1.1.4C procedure outcomes (including complications and any adverse events); and

1.1.5C medical record completeness and timeliness.

STANDARD – QI Oversight

1.2C The Medical Director, staff and/or an appointed QI Committee must provide oversight to the QI program including but not limited to review of the reports of QI evaluations and any corrective actions taken to address any deficiencies.

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Section 2C: Quality Improvement Measures

STANDARD – General QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C through 2.1.5C. All measures described need to be measured for consecutive cases over a period of time. A minimum of 30 cases must be reviewed annually.

2.1.1C Procedure/Test Appropriateness

2.1.1.1C The facility must evaluate the appropriateness of the procedures performed and categorize as:

i. appropriate;
ii. may be appropriate;
iii. rarely appropriate/usually not appropriate;
iv. not appropriate.

2.1.2C Technical Quality and Performance of the Procedure

2.1.2.1C completeness of the procedure;

2.1.2.2C documentation of adverse technical events such as equipment or device failure;

2.1.2.3C failure to perform the procedure;

2.1.2.4C quality of pre-procedure testing; and

2.1.2.5C adherence to the facility protocols.

2.1.3C Patient Safety

2.1.3.1C Accuracy of patient identification:

i. Use at least two patient identifiers when providing care, treatment or service.

2.1.3.2C Medication safety:

i. Label all medication with name, concentration and expiration date.
ii. Premixed pharmacologic and/or anesthetic agents must be labeled with content, concentration and expiration date if not prepared immediately before use.

2.1.3.3C Infection control measures consistent with CDC and OSHA guidelines.

2.1.3.4C Adherence to National Patient Safety Goals must be documented.

2.1.3.5C Review of patient radiation doses will be monitored and reviewed when exceeding 5Gy.

2.1.4C Procedure Outcomes (including complications or any adverse events)

2.1.4.1C The facility must have a written policy and process to track and document the outcomes of all patients evaluated and/or treated.

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2.1.4.2C All procedural outcomes in the patient medical record must be documented.

2.1.4.3C Must document all adverse events that occur within (30 days) post-procedure must be documented in a centralized location or in retrievable electronic medical records for review (download the VI Procedure Complications list at www.intersocietal.org/document/vi-procedure-complication-list).

2.1.4.4C Review of each case requiring referral outside the center for treatment of complications must be reviewed.

2.1.4.5C Filter removal success rate including number of attempts must be documented.

2.1.4.6C QoL and post procedure imaging outcomes are suggested.

2.1.4.7C Each center should have a peer review process to review adverse outcomes and a sample of each provider's interventions on a bi-annual basis with recommendations for mentorship remediation and suspension of privileges leading to termination if recurrent issues occur.

2.1.5C Medical Record Completeness and Timeliness

2.1.5.1C Time from completion of procedure to signature of final documentation completed within two days.

Section 3C: Quality Improvement Meeting *Guidelines*

2.1.5.4C Quality of life measurement is encouraged.

Example of vein-specific quality of life instruments include CIVIQ, VEINES Sym/QoL, the Aberdeen Varicose Vein Score and the Specific Quality-of-life and Outcome Response-Venous [SQOR-V]) questionnaire.

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Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

3.1C The facility must have a minimum of two QI meetings per year and must include the following:

3.1.1C Review, adjudication and documentation of all major and minor complications.

3.1.2C Case review of QI measures outlined in sections 2.1.1C through 2.1.5C.

3.1.2.1C All cases categorized as rarely or not appropriate must be documented and discussed.

3.1.3C Educational updates and additional QI-related topics should be discussed and documented.

3.1.4C Review and documentation of procedures exceeding established radiation dose thresholds (e.g., 5Gy).

3.1.5C Documentation of the review of the monthly emergency medication inspection log.

3.1.6C Verification of routine inspection of medical supplies/equipment must be documented.

3.1.7C All clinical staff must participate in at least one meeting per year.

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Section 4C: Quality Improvement Documentation

STANDARD – QI Documentation and Record Retention

4.1C The facility QI documentation must include but is not limited to:

- 4.1.1C the data for all of the QI measures above;
- 4.1.2C changes in procedures or policies as a result of this analysis;
- 4.1.3C minutes from the QI meetings; and
- 4.1.4C participant list (may include remote participation and/or review of minutes).
  - 4.1.4.1C Attestation must be obtained from staff members who cannot participate but have reviewed the documentation.

4.2C The QI documentation must be maintained and available for all appropriate personnel to review.

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Artificial Intelligence (AI) Guidance Document

To assure the quality and safety of care delivery when using AI applications for direct-patient care (clinical*) purposes, each facility should create and follow policies and procedures that address:

1. Training for personnel who use AI;
2. Security of AI software, updates, HIPAA considerations, etc.;
3. AI for Quality Improvement (if applicable);
4. Appropriate use for each AI application; and
5. Governance (authority to make decisions regarding AI implementation).

*Clinical use of AI includes image acquisition, image processing/enhancement, image interpretation, report generation, risk assessment of prognosis, patient history, identification of critical values/results and equipment quality control.

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