INTERSOCIETAL ACCREDITATION COMMISSION

VASCULAR INTERVENTIONAL

IAC Standards & Guidelines for Vein Center Accreditation

Accreditation Standards

AUGUST 2025

Introduction

The Intersocietal Accreditation Commission (IAC) accredits facilities that provide venous evaluation and 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 perform evaluation and management of venous disorders in order to ensure that the center meets benchmarks for quality based on resources, training and outcomes. Medical knowledge for the evaluation and management of venous disorders is required.

A 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 and utilizes venous duplex ultrasound diagnostic testing in an IAC or American College of Radiology (ACR) accredited facility. The center must meet the organizational requirements defined in this document. Under the supervision of the qualified Medical Director, there may be additional medical staff (MD or DO), Advanced Practice Providers [Physician Assistant (PA), Nurse Practitioner (NP)], nurses, ultrasound technologist/sonographers and/or ancillary personnel. All physicians, Advanced Practice Providers and nurses who perform venous interventions in the facility must be included in the application for accreditation as part of the medical staff.

Vein center accreditation is available in superficial venous evaluation and management. This area has a primary and secondary subset of skills. Primary procedures are required for accreditation. Secondary procedures may or may not be performed. If secondary procedures are not performed there must be a policy in place for referral of those procedures.

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 are the minimum standards for accreditation of a superficial venous center, and represent the minimum requirements to which an accredited facility is held accountable. In addition to all Standards listed below, the facility, including 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, 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.

Superficial: Primary Requirements

Must have the capability to provide within the vein center at least two of the four following procedures:

1. Sclerotherapy
2. Ambulatory phlebectomy/powered phlebectomy
3. Saphenous vein ablation
    a. may include surgical, endovenous thermal, endovenous non-thermal and/or ultrasound-guided chemical ablation

4. Non-operative management of chronic venous insufficiency with ulceration (CEAP Clinical classification C6)
    a. wound care including:
        i. debridement/bandaging and compression therapy

Superficial: Secondary Capabilities

May have the capability to provide the following procedures within the vein center in addition to primary requirements, but do not qualify for accreditation if they are the only procedures offered:

1. Stripping/ligation
2. Cutaneous LASER
3. Ultrasound-guided sclerotherapy
4. Perforating vein ablation

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*.

Physicians

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. The license must be current and unrestricted. In addition, they must be or have been certified by the American Board of Medical Specialties, American Osteopathic Association, the Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec. If board certification is not current, additional documentation will be required that must include the following:

- Three letters of recommendation from physicians who practice in the community and are familiar with the practice, based on referral and observation.
- If this Medical Director has hospital privileges, one of the three letters must come from the Chief of the Service.

(See Guidelines on Page 13 for further recommendations.)

1.1.1A Medical Director Required Training and Experience:

At the time of initial application for accreditation or at the time of appointment to the medical staff, he/she must have clinical experience in the management and treatment of venous disease and must meet either1.1.1.1A, 1.1.1.2A or 1.1.1.3A:

1.1.1.1A Performed a minimum of 200 cases over the previous three years in at least two of the four categories with a minimum of 50 cases per category:

- Sclerotherapy
- Ambulatory phlebectomy/powered phlebectomy
- Saphenous vein ablation
  - may include surgical, endovenous thermal, endovenous non-thermal and/or ultrasound-guided chemical ablation
- Non-operative management of chronic venous insufficiency with ulceration (CEAP Clinical classification C6)
  - wound care including:
    - debridement/bandaging and compression therapy

i. The cases must be documented with a case log.

OR

1.1.1.2A If the Medical Director has successfully completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship for which venous disease, venous interventional treatment and venous ultrasound training was included in the core curriculum within three years prior to the application date.

Return to Table of Contents

i. Performed a minimum of 100 cases over the previous three years in at least two of the four categories with a minimum of 50 cases per category:

- Sclerotherapy
- Ambulatory phlebectomy/powered phlebectomy
- Saphenous vein ablation
  - may include surgical, endovenous thermal, endovenous non-thermal and/or ultrasound-guided chemical ablation
- Non-operative management of chronic venous insufficiency with ulceration (CEAP Clinical classification C6)
  - wound care including:
    - debridement/bandaging and compression therapy

ii. The cases must be documented with a case log.

iii. A letter from the program director may be required to confirm completion of the fellowship and case log accuracy.

OR

1.1.1.3A American Board of Vein and Lymphatic Medicine (ABVLM) Certification

AND

1.1.1.4A A case log documenting the performance and/or direct supervision and findings of a minimum of 100 (focused, limited or complete) diagnostic venous ultrasounds.

AND

1.1.1.5A Qualifying and Continuing Medical Education (CME) Requirement:

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

Comment: If a meeting was not solely dedicated to venous disease, venous interventional treatment and/or venous ultrasound, only the related hours are to be included in the application for accreditation.

ii. If the Medical Director has successfully completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship for venous disease, interventional treatment and ultrasound training within three years prior to the application date, the CME requirement will be waived.

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

AND

1.1.1.6A The Medical Director must have current Basic Life Support certification, and if moderate/IV sedation is utilized, Advanced Cardiac Life Support certification is required.

1.1.2A Medical Director Responsibilities:

1.1.2.1A 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:

Return to Table of Contents

i. The Medical Director must provide oversight of patient safety.

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 via signature (or initials) and date on the reviewed document or manual.

iii. The Medical Director must review quality improvement (QI) documentation that includes at a minimum those requirements listed in Part C: Quality Improvement.

iv. The Medical Director may supervise the entire operation of the facility or delegate specific operations, but is responsible for assuring compliance of medical and other staff to the Standards outlined in this document.

v. If the Medical Director is off-site, he/she must have at least a weekly physical presence in the vein center to 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. The license must be current and unrestricted. In addition, they must be or have been certified by the American Board of Medical Specialties, American Osteopathic Association, the Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec. If board certification is not current, additional documentation will be required that must include all of the following:

- Three letters of recommendation from physicians who practice in the community and are familiar with the practice based on referral and observation.
- If this medical staff member has hospital privileges, one of the three letters must come from the Chief of the Service.

(See Guidelines on Page 13 for further recommendations.)

1.2.1A Medical Staff Required Training and Experience:

At the time of initial application for accreditation or at the time of appointment to the medical staff, he/she must have clinical experience in the management and treatment of venous disease and must meet either 1.2.1.1A, 1.2.1.2A or 1.2.1.3A:

1.2.1.1A Performed a minimum of 100 cases over the previous three years in at least one out of the four categories:

- Sclerotherapy
- Ambulatory phlebectomy/powered phlebectomy
- Saphenous vein ablation
  - may include surgical, endovenous thermal, endovenous non-thermal and/or ultrasound-guided chemical ablation
- Non-operative management of chronic venous insufficiency with ulceration (CEAP Clinical classification C6)
  - wound care including:
    - debridement/bandaging and compression therapy

ii. The cases must be documented with a case log.

OR

1.2.1.2A If the medical staff member has successfully completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship for which

Return to Table of Contents

venous disease, venous interventional treatment and venous ultrasound training was included in the core curriculum within three years prior to the application date.

i. Performed a minimum of 50 cases over the previous three years in at least one out of the four categories:

- Sclerotherapy
- Ambulatory phlebectomy/powered phlebectomy
- Saphenous vein ablation
  - may include surgical, endovenous thermal, endovenous non-thermal and/or ultrasound-guided chemical ablation
- Non-operative management of chronic venous insufficiency with ulceration (CEAP Clinical classification C6)
  - wound care including:
    - debridement/bandaging and compression therapy

ii. The cases must be documented with a case log.

iii. A letter from the program director may be required to confirm completion of the fellowship and case log accuracy.

OR

1.2.1.3A American Board of Vein and Lymphatic Medicine (ABVLM)

AND

1.2.1.4A A case log documenting the performance and documentation of the findings in the clinical record of a minimum of 30 cases of (focused, limited or complete) for the performance and/or direct supervision of diagnostic venous ultrasounds.

AND

1.2.1.5A Qualifying and Continuing Medical Education (CME) Requirements:

i. The medical staff must obtain a minimum of 30 Category I CME credit hours related to venous disease, venous interventional treatment and/or venous ultrasound, in the past three years.

Comment: If a meeting was not solely dedicated to venous disease, venous interventional treatment and/or venous ultrasound, only the related hours are to be included in the application for accreditation.

ii. If the medical staff member has successfully completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship for venous disease, interventional treatment and ultrasound training within three years prior to the application date, the CME requirement will be waived.

AND

1.2.1.6A All medical staff must have current Basic Life Support certification, and if moderate/ IV sedation is utilized, Advanced Cardiac Life Support certification is required.

1.2.2A Provisional Medical Staff:

1.2.2.1A The qualified Medical Director may appoint a qualified staff member(s) as provisional staff who meets all of the above criteria with the exception of the

Return to Table of Contents

required procedure performance volumes. 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.

1.2.3A Medical Staff Responsibilities:

1.2.3.1A The medical staff is responsible for performing venous evaluation, management and treatment. Responsibilities may include, but are not limited to:

i. The medical staff must comply with all of the facility's policies, procedures, and/or protocols and to the Standards outlined in this document.
ii. The medical staff must be responsible for equipment training and inspection to ensure safe operating conditions as specified by the manufacturer's guidelines and the Medical Director.
iii. The medical staff must participate in the facility's comprehensive Quality Improvement (QI) program.

Advanced Practice Provider

All non-physician personnel within the facility must have a specific job description on file and must be evaluated annually for performance and competency.

STANDARD – Advanced Practice Provider (APP)

1.3A 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 as well as those determined by local, state and/or federal regulations within the scope of practice of an APP.

(See Guidelines on Page 13 for further recommendations.)

1.3.1A APP Required Training and Experience:

1.3.1.1A The APP must meet one of the following criteria for required certification:

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

1.3.1.2A The APP must obtain a minimum of 30 Category I CME credit hours related to venous disease, venous interventional treatment and venous ultrasound, in the prior three years.

Comment: If a meeting was not solely dedicated to venous disease, venous interventional treatment and/or venous ultrasound, only the related hours are to be included in the application for accreditation.

1.3.1.3A The APP must have current Basic Life Support certification, and if performing procedures with moderate/IV sedation, Advanced Cardiac Life Support certification is required (even if another provider participating in moderate/IV sedation cases already possesses such certification).
Comment: Additional credentials may be required as they become available.

1.3.1.4A APPs may perform the following superficial vein skills under the personal supervision[1] of a qualified medical staff member:

Return to Table of Contents

i. patient evaluation and management;
ii. visual sclerotherapy;
iii. ambulatory phlebectomy;
iv. saphenous vein ablation.

1.3.1.5A APP may perform certain skills with direct or general supervision within the vein center after qualifying in at least one of three pathways summarized below or as shown in Table 1.3.1.5A on page 10.

The APP must fulfill one of the following qualifying pathways for each skill, based on their skill specific prior experience, in order to be considered credentialed to practice that skill with less than personal supervision:

i. New providers without prior experience:

- APP does not have prior experience in superficial vein disease/procedures.

OR

ii. Provider with experience in a facility other than the applicant facility:

- APP must have a case log of their prior experience that includes outcomes and level of supervision. An attestation of experience and level of supervision by a prior supervising physician may also satisfy this requirement.

OR

iii. Provider with experience in the applicant facility:

- APP has experience and training in the treatment of superficial vein disease/procedures under supervision of the current Medical Director, or one of the medical staff.
- APP must have a case log of their prior experience which include outcomes and level of supervision and an attestation of the Medical Director of their prior experience.

Table 1.3.1.5A

Skill	New providers without prior skill specific experience	Provider with skill specific experience in a facility other than the applicant facility	Provider with skill specific experience in the applicant facility
Evaluation and Management of Venous Disease	A minimum of 60* cases evaluated over the previous three years, as follows: The APP must shadow** a minimum of 30* cases of evaluation and management performed by a qualified*** physician. These cases must include personal observation of the performance and interpretation of the patient's diagnostic venous ultrasound examination(s). The remaining 30* cases must be performed under direct supervision of a qualified*** physician and include interpretation of any ultrasound studies.	A minimum of 25* cases evaluated over the previous three years, as follows: The APP must shadow** a minimum of 10* cases of evaluation and management performed by a qualified*** physician. These cases must include personal observation of the performance and interpretation of the patient's diagnostic venous ultrasound examination. The remaining 15* cases must be performed under direct supervision of a qualified*** physician. .	A minimum of 25* cases evaluated over the previous three years as follows: The APP must shadow** a minimum of 10 cases of evaluation and management performed by a qualified*** physician. These cases must include personal observation of the performance and interpretation of the patient's diagnostic venous ultrasound examination(s). The remaining 15* cases must be performed under direct supervision of a qualified*** physician. .
Visual Sclerotherapy	A minimum of 30* cases over the previous three years under personal supervision[1] of a qualified** physician, APP, or	A minimum of 10* cases over the previous three years under personal supervision[1] of a qualified*** physician, APP, or nursing staff	A minimum of 10* cases over the previous three years under personal[1], direct[2], or general supervision[3] of a qualified*** physician, APP, or

Return to Table of Contents

	nursing staff member designated by the Medical Director.	member designated by the Medical Director. .	nursing staff member designated by the Medical Director.
Ambulatory Phlebectomy	A minimum of 25* cases over the previous three years under personal supervision[1] of a qualified*** physician.	A minimum of 10* cases over the previous three years under personal supervision[1] of a qualified*** physician.	A minimum of 10* cases over the previous three years under personal[1] or direct supervision[2] of a qualified*** physician.
Ultrasound-guided Foam Sclerotherapy	A minimum of 150* cases over the previous three years under personal supervision[1] of a qualified*** physician. OR A minimum of 50* cases over the previous three years under personal supervision[1] of a qualified*** physician if the APP holds an appropriate credential in vascular testing (RVT, RVS, RT(VS), RPhS).	A minimum of 50* cases over the previous three years under personal supervision[1] of a qualified*** physician. OR A minimum of 50* cases over the previous three years under direct supervision[2] if the APP holds an appropriate credential in vascular testing (RVT, RVS, RT(VS), RPhs). OR A minimum of 50*cases over the previous three years under direct supervision[2] if performed with a credentialed vascular sonographer (RVT, RVS, RT(VS), RPhs).	A minimum of 50* cases over the previous three years under personal[1] supervision[2] of a qualified medical staff member. OR A minimum of 50* cases over the previous three years under direct supervision[2] if the APP holds an appropriate credential in vascular testing (RVT, RVS, RT(VS), RPhs). OR A minimum of 50*cases over the previous three years under direct supervision[2] if performed with a credentialed vascular sonographer (RVT, RVS, RT(VS), RPhs).
Wound Care	A minimum of 10* cases over the previous three years under personal supervision[1] of a qualified*** physician, APP, or nurse designated by the Medical Director.	A minimum of 10* cases over the previous three years under personal supervision[1] of a qualified*** physician, APP, or nurse designated by the Medical Director.	A minimum of 10* cases over the previous three years under personal[1], direct[2], or general supervision[3] of a qualified*** physician, APP, or nurse designated by the Medical Director.
(*) Each case performed in the current or prior vein center that is being presented to fulfill a case volume requirement should be kept in a case log which includes treating provider, supervising medical staff member, case, outcome, complications and level of supervision. The log must be available for review upon request. *(**) Advanced practice provider must observe the physician obtaining history, physical exam, reviewing the imaging studies, and making management recommendations to the patient.* *(***) Qualified staff members include physicians, advanced practice providers, and nurses who have met the criteria to perform cases under general supervision.*			

1.3.1.6A Ongoing skill specific supervision requirements (once APP has been credentialed in a specific skill(s) as described above in 1.3.1.5A):

i. Evaluation and management of venous disease must be performed under personal[1], direct[2] or general supervision[3] of a qualified medical staff member.

ii. Visual sclerotherapy must be performed under personal[1], direct[2] or general supervision[3] of a qualified medical staff member.

iii. Ambulatory phlebectomy must be performed under personal[1] or direct supervision[2] of a qualified medical staff member.

iv. Ultrasound-guided foam sclerotherapy must be performed under personal supervision[1] of a qualified medical staff member.

OR

Cases may be performed under direct supervision[2] if the APP holds an appropriate credential in vascular testing (RVT, RVS, RT(VS), RPhS).

OR

Cases may be performed under direct supervision[2] if performed with a credentialed vascular sonographer (RVT, RVS, RT(VS), RPhS).

v. Saphenous vein ablation must be performed under personal supervision[1] of a qualified medical staff member.

vi. Wound care must be performed under personal[1], direct[2] or general supervision[3] of a qualified medical staff member.

1.3.1.7A In addition to fulfilling the necessary requirements above, a case log must be maintained that documents skills performed, including the level of supervision,

Return to Table of Contents

clinical outcomes and complications in each case. The case log must be reviewed by the Medical Director during the bi-annual QI meeting.

1.3.2A Provisional APP:

1.3.2.1A 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 procedure performance volumes and CME. All procedures for each applicable skill must be performed under the personal supervision[1] of a qualified physician until a qualifying pathway and CME requirements are met. The Medical Director will be responsible for review of the provisional APP including bi-annual review of the case log including outcomes at the bi-annual QI meeting. The provisional APP must attain full APP status prior to reaccreditation.

Terminology used for level of supervision:

[1] Personal Supervision: Medical staff member in attendance in the room during the procedure.

[2] Direct Supervision: Medical staff member must be present in the office suite; immediately available.

[3] General Supervision: Medical staff member presence is not required during the procedure but should be available by phone.

STANDARD – Nursing Staff

1.4A 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.

(See Guidelines on Page 13 for further recommendations.)

1.4.1A Nursing Staff Required Training and Experience:

Table 1.4.1A

Skill	New providers without prior skill specific experience	Provider with skill specific experience in a facility other than the applicant facility	Provider with skill specific experience in the applicant facility
Visual Sclerotherapy	A minimum of 30* cases evaluated over the previous three years, as follows: The nurse must shadow** a minimum of 15* cases of visual sclerotherapy performed by a qualified*** physician. The remaining 15* cases must be performed under direct supervision of a qualified*** physician, APP, or nurse designated by the Medical Director.	A minimum of 10* cases evaluated over the previous three years, as follows: The nurse must shadow** a minimum of 5* cases of visual sclerotherapy performed by a qualified*** physician. The remaining 5* cases must be performed under direct supervision of a qualified*** physician, APP, or nurse designated by the Medical Director.	A minimum of 10* cases evaluated over the previous three years, as follows: The nurse must shadow** a minimum of 5* cases of visual sclerotherapy performed by a qualified*** physician. The remaining 5* cases must be performed under direct supervision of a qualified*** physician, APP, or nurse designated by the Medical Director.
Wound Care	A minimum of 10* cases over the previous three years under personal supervision[1] of a qualified** physician, APP. or nursing staff member designated by the Medical Director.	A minimum of 10* cases over the previous three years under personal supervision[1] of a qualified*** physician or an APP, or nursing staff member designated by the Medical Director.	A minimum of 10* cases over the previous three years under personal[1], direct[2], or general supervision[3] of a qualified*** physician or an APP, or nursing staff member designated by the Medical Director.

Return to Table of Contents

(*) Each case performed in the current or prior vein center that is being presented to fulfill a case volume requirement should be kept in a case log which includes treating provider, supervising medical staff member, case, outcome, complications and level of supervision. The log must be available for review upon request.

(**) Nurse must observe the physician performing visual sclerotherapy or wound care.

(***) Qualified staff members include physicians, advanced practice providers, and nurses who have met the criteria to perform cases under general supervision.

1.4.2A Nursing Staff Qualifying and Continuing Education (CE/CME) Requirements:

1.4.2.1A All nursing staff must obtain a minimum of 30 contact hours/Category 1 CME with at least 15 CE/CME related to venous disease in the past three years. All CE hours must be approved (i.e., AMA Category I, SVU, SDMS, American Nurses Credentialing Center (ANCC-Category I).

Comment: If a meeting was not solely dedicated to venous disease, venous interventional treatment and/or venous ultrasound, only the related hours are to be included in the application for accreditation.

1.4.2.2A The CE/CME requirement will be waived 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);
iii. been employed in the facility less than one year.

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

1.4.3A Provisional Nursing Staff:

1.4.3.1A The qualified Medical Director may appoint a qualified nurse as provisional staff who meets all of the above criteria with the exception of the required procedure performance volumes. The Medical Director will be responsible for review of the provisional nurse including biannual review of case log including outcomes. The provisional nursing staff member must attain full nursing status prior to reaccreditation.

STANDARD – Ultrasound Technologist/Sonographer

1.5A The ultrasound technologist/sonographer is a credentialed professional who possesses advanced ultrasound knowledge about the diagnosis of acute and chronic venous disorders and works under the direction of the Medical Director. A technologist must meet the required training and experience qualifications as outlined in this document.

1.5.1A Ultrasound Technologist Required Training and Experience:

1.5.1.1A Must have an appropriate level of training and experience and must have a valid appropriate credential in vascular testing:

i. Registered Vascular Technologist (RVT);
ii. Registered Vascular Specialist (RVS);
iii. Registered Technologist Vascular Sonography [RT(VS)];
iv. Registered Phlebology Sonographer (RPhS).

Return to Table of Contents

1.5.1.2A Each technologist must have performed a minimum of 100 diagnostic peripheral venous duplex examinations (half of which must be complete examinations for reflux) in the previous three years.

1.5.2A Ultrasound Technologist Responsibilities:

1.5.2.1A Ultrasound technologist responsibilities include:

i. performance and documentation of clinical examinations;
ii. demonstration of appropriate sterile technique knowledge and skills for use when assisting a physician with a sterile procedure.

1.5.3A Ultrasound Technologist Continuing Medical Education (CME) Requirements:

1.5.3.1A The technologist must obtain at least 15 CME credit hours every three years relevant to venous disease, venous interventional treatment and/or peripheral venous ultrasound. All hours must be approved CME (i.e., AMA Category I, SVU, SDMS).

1.5.3.2A Documentation of CME credits must be kept on file and available for inspection.

1.5.3.3A The CME requirement will be waived if:

i. the technologist acquired an appropriate vascular credential within the previous three-year period.

STANDARD – Ancillary Personnel

1.6A The facility must ensure that adequately supervised ancillary personnel are available to perform safe and effective patient care appropriate for the level of service, as designated by the Medical Director.

1.6.1A Ancillary Personnel Required Training and Experience:

1.6.1.1A Ancillary personnel may consist of, but are not limited to:

i. technical/medical assistants;
ii. clerical and administrative assistants;
iii. computer support staff;
iv. equipment support staff (i.e., biomedical).

Return to Table of Contents

Section 1A: Personnel and Supervision *Guidelines*

1.1A and 1.2A Participation in a venous registry is encouraged, but is not mandatory.

1.3A Advanced Practice Provider responsibilities may include:

- *obtaining a record of anatomical, pathological and/or physiologic data (CEAP classification);*
- *participation in vein center safety practices including, but not limited to, safe use of equipment and review of patient outcomes and complications;*
- *knowledge and maintenance of sterile technique;*
- *knowledge regarding compression techniques, including stockings and bandaging;*
- *medication administration;*
- *post-procedure discharge instructions;*
- *phone triage;*
- *patient education; and*
- *assisting a staff physician with image-guided sclerotherapy, ambulatory phlebectomy, endovenous ablation and other invasive procedure.*

1.4A Nursing staff responsibilities may include:

- *reviewing and/or recording pertinent patient history and supporting clinical data;*
- *obtaining a record of anatomical, pathological and/or physiologic data (CEAP classification);*
- *participation in vein center safety practices including but not limited to safe use of equipment and review of patient outcomes and complications;*
- *knowledge and maintenance of sterile technique;*
- *medication administration;*
- *fitting patients for elastic compression;*
- *application of inelastic compression and patient education;*
- *post-procedure discharge instructions;*
- *phone triage;*
- *patient education;*
- *assisting a staff physician with image-guided sclerotherapy, ambulatory phlebectomy, endovenous ablation and other invasive procedures; and*
- *other procedures and duties, as assigned*

Return to Table of Contents

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;
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;

Return to Table of Contents

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 one hour 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.

Return to Table of Contents

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 3.4A and also Standard 3.2A 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.

Return to Table of Contents

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.

Return to Table of Contents

3.3A Emergency Equipment

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:

Return to Table of Contents

3.4.5.1A non-invasive blood pressure;

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;

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.

Return to Table of Contents

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 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.

Return to Table of Contents

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3. Occupational Safety and Health Standards – Toxic and Hazardous Substances (Bloodborne Pathogens). United States Department of Labor Occupational Safety and Health Administration. www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

Return to Table of Contents

Part B: Process

Section 1B: Procedures

STANDARD – Procedure Overview

1.1B These Standards include the minimum requirements for the performance of the following superficial venous procedures:

1. Sclerotherapy
2. Ambulatory phlebectomy/powered phlebectomy
3. Saphenous vein ablation
   a. may include surgical, endovenous thermal, endovenous non-thermal and/or ultrasound-guided chemical ablation
4. Non-operative management of chronic venous insufficiency with ulceration (CEAP Clinical classification C6)
   a. wound care
   b. debridement/bandaging and compression therapy

1.2B General Required Documentation

1.2.1B Pre-Treatment Documentation

1.2.1.1B 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:

i. a history of the venous disorders
- clinical class score (CEAP) and Venous Clinical Severity Score (VCSS) at baseline for the affected limb or limbs, repeat at completion of treatment or as indicated
- One QOL measure (CIVIQ, VEINES, VVSymQ, AVVQ).
- a review of past medical history
  - medications
  - allergies
- venous history
  - family history of venous disease
- prior venous treatments, including outcomes of those treatments
  - include prior use of compression
- previous venous imaging studies, if available for review

ii. additional laboratory, imaging and/or consultations, as indicated
iii. a directed physical exam
iv. functional (reflux) ultrasound of the superficial, perforator and deep veins
v. treatment plan
vi. pre-treatment photographs are strongly recommended as a baseline for comparison after treatment.

1.2.1.2B Any changes in medical history, medications, allergies must be documented with each encounter.

Return to Table of Contents

1.2.1.3B Must use accepted nomenclature for anatomy.

1.2.1.4B Duplex ultrasound imaging of the venous system must be performed prior to treatment for all patients with C2 or higher disease and as indicated in selected patients with C0 or C1 disease.

i. Must use an IAC or American College of Radiology (ACR) accredited facility for venous duplex ultrasound diagnostic testing.

1.2.2B Lower extremity venous duplex for reflux must include:

1.2.2.1B Transverse grayscale images without and with transducer compressions (when anatomically possible or not contraindicated) must be documented as required by the protocol and must include at a minimum:

i. common femoral vein;
ii. saphenofemoral junction;
iii. proximal femoral vein;
iv. mid femoral vein;
v. distal femoral vein;
vi. great saphenous vein;
vii. popliteal vein;
viii. small saphenous vein;
ix. additional images to document areas of suspected reflux and as required by the protocol.

1.2.2.2B Spectral Doppler waveforms with the extremity(s) in a dependent position (refer to Standard 1.2.2.5B), demonstrating baseline flow and response to distal augmentation and if reflux is present, duration of retrograde flow must be measured with calipers and documented as required by the protocol and must include at a minimum:

i. common femoral vein;
ii. saphenofemoral junction;
iii. great saphenous vein at proximal thigh;
iv. great saphenous vein at knee;
v. great saphenous vein below knee;
vi. femoral vein mid thigh;
vii. popliteal vein;
viii. anterior accessory saphenous vein (when identified);
ix. small saphenous vein at the junction of the deep system (when visualized);
x. small saphenous vein at mid calf;
xi. perforator vein waveforms in the setting of active or healed venous ulcers, as required by the protocol;
xii. additional waveforms as required by the protocol.

1.2.2.3B Transverse grayscale images of diameter measurement must be documented with the extremity(s) in a dependent position and must include at a minimum:

i. saphenofemoral junction;
ii. great saphenous vein at proximal thigh;
iii. great saphenous vein at knee;

Return to Table of Contents

iv. anterior accessory saphenous vein (when identified);

v. small saphenous vein at the junction of the deep system (when visualized). If not visualized there, the small saphenous vein at the mid calf must be documented.

1.2.2.4B Proper measurements as required by the protocol:

i. vein diameter measurements must:

- be acquired with the extremity(s) in a dependent position;
- be acquired in transverse anterior wall to posterior wall, consistently, or as required by the protocol;
- as required by the protocol for active or healed venous ulcers, perforator vein diameter measurements must be acquired where the perforator traverses the deep fascia;
- assure that no external pressure is applied to the vein.

1.2.2.5B proper patient positioning:

i. The limb must be placed in a dependent position. Standing is the preferred position if not constrained by the patient's physical condition. Sitting or reverse Trendelenburg may be used if the patient cannot stand. Patient position must be noted in the final report.

STANDARD – Procedure Requirements

1.3B Required Pre-Procedure Documentation:

1.3.1B Must be documented in the medical record:

1.3.1.1B Procedure, limb and vessel-specific informed consent must be obtained, signed by the patient/legal proxy, and provider prior to the procedure. Consent must be obtained by the provider who can attest to having a conversation with the patient about the risks/benefits and expectations of the procedure.

1.3.1.2B Assessment and documentation of the correct patient, site and procedure immediately before initiation of the procedure

1.4B Required Procedure Documentation:

1.4.1B Must include and be documented in the medical record:

1.4.1.1B name of the provider(s) performing the procedure as well as the supervising provider, if applicable;

1.4.1.2B a summary of the procedure;

i. Documentation may be facilitated by recording a diagram of the extremity treated.

1.4.1.3B any immediate complications or adverse events;

1.4.1.4B the patient's status at the end of the procedure;

1.4.1.5B veins treated (spider, reticular, varicose tributaries, great saphenous, small saphenous, perforator, etc.) and extent/length as indicated;

Return to Table of Contents

1.4.1.6B laterality and site(s).

1.5B Required Post-Procedure Documentation and Patient Instructions:

1.5.1B Must include and be documented in the medical record:

1.5.1.1B procedure performed;

1.5.1.2B post-procedure care and expectations;

1.5.1.3B possible adverse events or complications which may require contact with a health care provider;

1.5.1.4B directions for contact to provider or covering medical team at any hour;

1.5.1.5B contact information to access the health care team;

1.5.1.6B dressings and wound care;

1.5.1.7B type and duration of compression;

1.5.1.8B patient activity, ambulation and exercise;

1.5.1.9B air and car travel restrictions;

1.5.1.10B management of post-procedure pain;

1.5.1.11B follow-up duplex ultrasound exam appointment, if appropriate;

1.5.1.12B a follow-up appointment (as required by the facility's protocol) either in person, by telephone, or electronic communication with a medical staff member, advanced practice provider, or nursing staff member must be documented and include one QOL measure (CIVIQ, VEINES, VVSymQ, AVVQ) and VCSS (when follow-up occurs in person).

1.5.2B A record of specific complications post-procedure complications:

1.5.2.1B allergic reactions (including skin reactions from glue);

1.5.2.2B deep vein thrombosis;

1.5.2.3B superficial thrombophlebitis;

1.5.2.4B extension of thrombus into the deep veins, Endovenous Heat Induced Thrombus (EHIT), Endovenous Glue Induced Thrombosis (EGIT);

1.5.2.5B skin burns, skin ulcers (sclerotherapy) and parasthesias;

1.5.2.6B wound infections.

1.6B **Sclerotherapy**:

1.6.1B Prior to Performance of the Procedure:

1.6.1.1B Appropriate pharmacologic agents, as defined by the procedure:

i. an adequate supply of sclerosants;

Return to Table of Contents

ii. if an FDA-approved liquid sclerosant is available, it must be used rather than a compounded version of the same agent.
    - Compounded sclerosants may be used when a higher concentration is needed for an individual patient than is available in an FDA-approved sclerosant.

iii. premixed solutions must be dated and marked to identify the sclerosant and the sclerosant concentration;

iv. must follow manufacturer recommendations regarding agent expiration date.

1.6.1.2B Appropriate supplies, as defined by the procedure:

i. lighting, magnification, gauze, syringes, needles, gowns, gloves, eye protection, etc.;

ii. ultrasound imaging equipment.

1.6.2B <u>During the Performance of the Procedure</u>:

1.6.2.1B Sclerotherapy technique procedure must be performed using clean technique.

1.6.2.2B During ultrasound-guided chemical ablation, visualization of proper needle placement and sclerosant delivery must be observed into the target vein.

1.6.3B <u>Sclerotherapy Procedure-Specific Documentation</u>:

1.6.3.1B Required procedure-specific documentation must include:

i. total volume of sclerosants(s);

ii. sclerosant concentration(s);

iii. ultrasound-guidance (if used).

1.7B **<u>Ambulatory Phlebectomy</u>**:

1.7.1B <u>Prior to Performance of the Procedure</u>:

1.7.1.1B Appropriate surgical instruments, as defined by the procedure.

1.7.1.2B Appropriate supplies, as defined by the procedure:

i. gauze, syringes, needles, gowns, gloves, mask, eye protection, sterile drapes, etc.

1.7.1.3B Appropriate pharmacologic and anesthetic agents, as defined by the procedure:

i. premixed pharmacologic and/or anesthetic agents must be labeled with content, concentration and expiration date if not prepared immediately before use.

1.7.1.4B Varicose veins must be marked immediately prior to the procedure.

1.7.1.5B Sterile prep of the treatment area.

1.7.2B <u>During the Performance of the Procedure</u>:

1.7.2.1B Appropriate ambulatory phlebectomy technique using hemostatic compression.

1.7.3B <u>Ambulatory Phlebectomy Procedure-Specific Documentation</u>:

Return to Table of Contents

1.7.3.1B Required procedure-specific documentation must document:

i. any use of ultrasound-guidance;
ii. location of varicosities;
iii. number of incisions;
iv. pharmacologic and/or anesthetic agents used, including the volume and concentration of tumescence.

1.8B **Endovenous Thermal Ablation (EVTA)**

1.8.1B If endovenous LASER is performed, the LASER must be U.S. Food and Drug Administration (FDA) cleared.

1.8.1.1B Eye protection for the specific LASER wavelength must be used by all staff in the room and the patient.

1.8.1.2B LASER safety signage must be displayed in accordance with Occupational Safety and Health Administration (OSHA) and state regulations.

1.8.2B If endovenous radiofrequency is performed, the radiofrequency generator with appropriate catheters must be FDA approved.

1.8.3B Prior to Performance of the Procedure:

1.8.3.1B Appropriate surgical instruments and supplies to include, but are not limited to:

i. sterile thermal ablation tools;
ii. associated generator equipment.

1.8.3.2B Appropriate supplies as defined by the procedure:

i. gauze, syringes, needles, gowns, gloves, mask, eye protection, sterile drapes, etc.

1.8.3.3B Appropriate pharmacologic and anesthetic agents and supplies:

i. Premixed pharmacologic and/or anesthetic agents must be clearly labeled.
ii. Pre-drawn syringes and basins must be clearly labeled.

1.8.3.4B Ultrasound imaging equipment as defined by the procedure.

1.8.3.5B Sterile prep of the treatment area.

1.8.4B During the Performance of the Procedure:

1.8.4.1B Adherence to IFU (instructions for use) or published guidelines for the performance of all ablation procedures.

1.8.4.2B Visualization of proper catheter placement into the target vein with ultrasound-guidance.

1.8.5B EVTA Procedure-Specific Documentation:

1.8.5.1B Required procedure-specific documentation must include:

i. pharmacologic and/or anesthetic agents used, including the volume and concentration of tumescence;

Return to Table of Contents

ii. use of ultrasound-guidance;
iii. the starting and ending time of treatment;
iv. the length of vein treated;
v. catheter insertion site(s);
vi. the energy deposited, RF cycles used or RF time; LASER Joules.

Comment: If concurrent ambulatory phlebectomy or sclerotherapy is performed all elements of their protocols and documentation need to be maintained as well.

1.9B **Endovenous Non-Thermal Non-Tumescent Ablation (NTNT) Procedure**

1.9.1B If endovenous non-thermal non-tumescent ablations are performed, the method, product and required instrumentation must be U.S. Food and Drug Administration (FDA) cleared, or used with an appropriate Investigational Device Exemption (IDE) or in a clinical trial.

1.9.2B Prior to Performance of the Procedure:

1.9.2.1B Appropriate instruments and supplies to include, but are not limited to:

i. sterile ablation tools;
ii. associated equipment.

1.9.2.2B Appropriate supplies as defined by the procedure:

i. gauze, needles, gowns, gloves, mask, sterile drapes, etc.

1.9.2.3B Appropriate pharmacologic agents and supplies:

i. ultrasound imaging equipment as defined by the procedure;
ii. sterile prep of the treatment area.

1.9.3B During the Performance of the Procedure:

1.9.3.1B Adherence to the manufacturer recommendations and/or IFU (instructions for use) or published guidelines for the performance of all non-thermal non-tumescent ablation procedures.

1.9.3.2B Visualization of proper catheter placement into the target vein with ultrasound-guidance.

1.9.4B NTNT Ablation Procedure-Specific Documentation:

1.9.4.1B Required procedure-specific documentation must include:

i. pharmacologic agents, if used including the volume and concentration;
ii. use of ultrasound-guidance;
iii. the starting and ending time of treatment;
iv. the length of vein treated;
v. catheter insertion site(s).

1.10B **Non-operative Management of Chronic Venous Insufficiency with Ulceration (CEAP Clinical Classification C6)**

- wound care including:
  - debridement/bandaging and compression therapy

Return to Table of Contents

1.10.1B Prior to Performance of the Procedure:

1.10.1.1B Appropriate supplies as defined by the procedure.~~:~~

1.10.2B During the Performance of the Procedure:

1.10.2.1B Standard treatment technique(s) must be used.

1.10.3B Management of Chronic Venous Insufficiency Procedure-Specific Documentation:

1.10.3.1B Post-procedure specific required documentation must include, but is not limited to:

i. dressing utilized;
ii. medications;
iii. a description of the ulcer, ulcer management and changes noted compared to prior visit, as indicated.

STANDARD – Procedure Volumes

1.11B The procedure volume must be sufficient to maintain proficiency in procedure performance.

1.11.1B The facility must have performed at least 50 superficial venous procedures over the preceding one-year period in at least two of the four categories. There must be a minimum of 25 cases per category to be considered eligible for accreditation:

1.11.1.1B Superficial venous categories:

i. Sclerotherapy
ii. Ambulatory phlebectomy/powered phlebectomy
iii. Saphenous vein ablation
   - may include surgical, endovenous thermal, endovenous non-thermal and/or ultrasound-guided chemical ablation
iv. Non-operative management of chronic venous insufficiency with ulceration (CEAP Clinical classification C6)
   - wound care including:
     - debridement/bandaging and compression therapy

Return to Table of Contents

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

Comment: Download the Vein Center Procedure Complications list intersocietal.org/document/vein-procedure-complication-list).

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.

Return to Table of Contents

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 are recommended to be reviewed annually using the IAC QI Self-Assessment Tool.

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.

2.1.1.2C The facility must evaluate the appropriateness of the procedures performed using multi-societal appropriate use criteria.[8]

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;

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 services.

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.

2.1.4C 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; this includes patients referred to a wound care center.

Return to Table of Contents

2.1.4.2C Must document all procedural outcomes in the patient medical record pre- and post-treatment. This includes VCSS and one QOL measure (CIVIQ, VEINES, AVVQ) or other VPROM.

2.1.4.3C Must document all adverse events that occur within (30 days) post-procedure in a centralized location or in retrievable electronic medical records for review.

Comment: Download the Vein Center Procedure Complications list at intersocietal.org/document/vein-procedure-complication-list.

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

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 weeks.

Return to Table of Contents

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 never appropriate must be documented and discussed.

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

3.1.4C Documentation of the review of the monthly emergency medication inspection log.

3.1.5C Verification of routine inspection of medical supplies/equipment must be documented.

3.1.6C All clinical staff must participate in at least one meeting per year.

Return to Table of Contents

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).

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

Return to Table of Contents

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Return to Table of Contents

Appendix

Compression Therapy: Telangiectasia or more severe signs of chronic venous insufficiency or lymphedema.

Endovenous Ablation: Incompetent veins of or related to the saphenous system (valve closure time >500 ms as demonstrated by duplex ultrasound) filling a varicose reservoir with either symptoms of chronic venous insufficiency (pain, tenderness, edema, or Clinical Class 4-6 skin changes) or aesthetic concerns.

Phlebectomy: Visible reticular or varicose veins with exclusion of great or small saphenous vein trunks.

Sclerotherapy: Visible telangiectasia or larger abnormal veins including reticular and varicose veins including truncal varicose veins.

Guidelines and Links:

- American College of Surgeons (ACS) - www.facs.org
- American Vein and Lymphatic Society (AVLS) - www.myavls.org
- American Venous Forum (AVF) - www.veinforum.org
- Society for Clinical Vascular Surgery (SCVS) - scvs.org
- Society for Vascular Medicine (SVM) - www.vascularmed.org
- Society for Vascular Nursing (SVN) - www.svnnet.org
- Society for Vascular Ultrasound (SVU) - www.svunet.org
- Society of Interventional Radiology (SIR) - www.sirweb.org

Return to Table of Contents

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.

Return to Table of Contents