



**IAC Standards & Guidelines for
Vein Center Accreditation:
Superficial Venous Evaluation
and Management**

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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.

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. *Guidelines are descriptions, examples, or recommendations that elaborate on the Standards. Guidelines are not required, but can assist with interpretation of the Standards.*

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.

Standards are printed in regular typeface in outline form. *Guidelines are printed in italic typeface in narrative form.*

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 content changes that were made as part of the October 1, 2020 revision. Facilities applying for accreditation after October 1, 2020 must comply with these new highlighted Standards.

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

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 Mediciens 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 14 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 either 1.1.1.1A, 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.

- 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:

- 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 Mediciens 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 14 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 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 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 14 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 supervision¹ of a qualified medical staff member:

- 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 9-10.

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 100* patients evaluated over the previous three years under personal supervision ¹ of a qualified medical staff member. At least 30* cases must include personal observation of that patient's diagnostic venous ultrasound examination(s).	A minimum of 25* patients evaluated over the previous three years under personal supervision ¹ of a qualified medical staff member.	A minimum of 25* patients evaluated over the previous three years under personal ¹ , direct ² , or general supervision ³ of a qualified medical staff member.

Visual Sclerotherapy	A minimum of 50* cases over the previous three years under personal supervision ¹ of a qualified medical staff member.	A minimum of 10* cases over the previous three years under personal supervision ¹ of a qualified medical staff member.	A minimum of 10* cases over the previous three years under personal ¹ , direct ² , or general supervision ³ of a qualified medical staff member.
Ambulatory Phlebectomy	A minimum of 50* cases over the previous three years under personal supervision ¹ of a qualified medical staff member.	A minimum of 10* cases over the previous three years under personal supervision ¹ of a qualified medical staff member.	A minimum of 10* cases over the previous three years under personal ¹ or direct supervision ² of a qualified medical staff member.
Ultrasound-guided Foam Sclerotherapy	<p>A minimum of 150* cases over the previous three years under personal supervision¹ of a qualified medical staff member.</p> <p>OR</p> <p>A minimum of 50* cases over the previous three years under personal supervision¹ of a qualified medical staff member if the APP holds an appropriate credential in vascular testing (RVT, RVS, RT(VS), RPhS).</p>	<p>A minimum of 50* cases over the previous three years under personal supervision¹ of a qualified medical staff member.</p>	<p>A minimum of 50* cases over the previous three years under personal¹ supervision² of a qualified medical staff member.</p> <p>OR</p> <p>A minimum of 50* cases over the previous three years under direct supervision² if the APP holds an appropriate credential in vascular testing (RVT, RVS, RT(VS), RPhs).</p> <p>OR</p> <p>A minimum of 50* cases over the previous three years under direct supervision² if performed with a credentialed vascular sonographer (RVT, RVS, RT(VS), RPhs).</p>
Wound Care	A minimum of 20* cases over the previous three years under personal supervision ¹ of a qualified medical staff member.	A minimum of 10* cases over the previous three years under personal supervision ¹ of a qualified medical staff member.	A minimum of 10* cases over the previous three years under personal ¹ , direct ² , or general supervision ³ of a qualified medical staff member.
<p><i>(*) 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 case, outcome, complications and level of supervision. The log must be available for review upon request.</i></p>			

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 personal¹, direct² or general supervision³ of a qualified medical staff member.
- ii. Visual sclerotherapy must be performed under personal¹, direct² or general supervision³ of a qualified medical staff member.
- iii. Ambulatory phlebectomy must be performed under personal¹ or direct supervision² of a qualified medical staff member.
- iv. Ultrasound-guided foam sclerotherapy must be performed under personal supervision¹ of a qualified medical staff member.

OR

Cases may be performed under direct supervision² if the APP holds an appropriate credential in vascular testing (RVT, RVS, RT(VS), RPhS).

OR

Cases may be performed under direct supervision² if performed with a credentialed vascular sonographer (RVT, RVS, RT(VS), RPhS).
- v. Saphenous vein ablation must be performed under personal supervision¹ of a qualified medical staff member.
- vi. Wound care must be performed under personal¹, direct² or general supervision³ 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,

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 supervision¹ of a qualified medical staff member 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: Physician in attendance in the room during the procedure.*

² *Direct Supervision: Physician must be present in the office suite; immediately available.*

³ *General Supervision: Physician 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 14 for further recommendations.)

1.4.1A **Nursing Staff Required Training and Experience:**

- 1.4.1.1A If performing visual sclerotherapy, a minimum of 50 cases must be documented over the previous three years.
- 1.4.1.2A If performing wound care, superficial debridement, bandaging and compression therapy, a minimum of 20 cases must be documented over the previous three years.
- 1.4.1.3A Attestation or a case log that documents evidence of supervised training in the above procedures must be available for review upon request.
- 1.4.1.4A All nursing staff must maintain current Basic Life Support certification

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

- 1.4.2.1A The nurse 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).

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 may include, but are not limited to:

- 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).

STANDARD – Required Protocols and Guidelines

- 1.7A There must be a written protocol for:
- 1.7.1A Each procedure performed in the facility with indications, contraindications, pretreatment evaluation and reporting outcomes.
- 1.7.2A Adherence to National Patient Safety Goals must be documented.
- 1.7.3A Treatment and or referral of patients with superficial venous thrombosis evaluation and management.
- 1.7.4A Treatment and/or referral of patients with DVT, arterial disease and complications of treatments provided in the vein center.
- 1.7.5A 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 (refer to Standards 2.2.4A, 2.2.5A and 2.2.6A).
- 1.7.6A The referral of patients who present with wounds that cannot be managed in the vein center.
- 1.7.7A Routine supply inventory of disposable supplies (e.g., catheters, LASER fibers, guide wires, sheaths, needles, syringes, contrast agent, medications) based on facility volume to assure that these supplies are readily available during a procedure.
- 1.7.8A Proper disposal of used or expired supplies.
- 1.8A There must be written guidelines for:
- 1.8.1A Intravenous access and administration of fluids and medications, if used.
- 1.8.2A Monitoring patients undergoing procedures using mild sedation (anxiolysis), if used.
- 1.8.3A Use of moderate sedation or greater, and must be in compliance with state regulations and [American Society of Anesthesiology \(ASA\) Guidelines](#).
- 1.8.3.1A There must be at least one person in the procedure room with Advanced Cardiac Life Support (ACLS) certification.

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;*
- *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;*
- *other procedures and duties, as assigned*

Section 2A: Physical Facilities

STANDARD – Physical Space

2.1A Adequate space must be provided for all operations of the facility so that patient comfort, safety, dignity, and privacy are ensured as well as staff comfort and safety. Procedure areas must have sufficient space, be well-maintained and clean.

2.1.1A Physical space requirements include, but are not limited to:

2.1.1.1A reception and patient/staff bathroom;

2.1.1.2A private patient examination areas;

2.1.1.3A in case of emergency, there must be adequate space for performing resuscitation;

2.1.1.4A adequate space, facility configuration and doorways for the emergency transport of patients from patient care areas and for the emergency exit of staff;

2.1.1.5A readily accessible hand washing/sanitation stations for staff;

2.1.1.6A procedure room;

2.1.1.7A patient records, reports and digital data storage areas.

Comment: The storage must ensure confidentiality of data and should be safe from fire/flood.

2.1.1.8A administration records and support areas;

2.1.1.9A equipment/supply storage areas.

STANDARD – Equipment and Instrumentation

2.2A Equipment and instrumentation used in the performance of venous interventions must be appropriate and in good working condition and inspected per the required local, state and/or federal regulations.

2.2.1A All equipment and instrumentation must be routinely inspected for safety and proper functionality and records of the inspections kept on file.

2.2.2A Equipment and instrumentation must include at a minimum:

2.2.2.1A Emergency equipment must be readily available within the facility and in close proximity to where vein center procedures are performed.

i. emergency cart/kit

- Must be opened and its contents inspected by the authorized personnel monthly. The monthly inspection must be documented and include:
 - the listing of all emergency supplies and equipment;
 - the name of the medication(s), including strength, quantity, lot number and expiration date;
 - the staff member's name who performed the inspection;
 - the inspection date.

- ii. emergency drugs (including a master list with verification of expiration date).
- 2.2.2.2A All emergency equipment must be clearly labeled and be for emergency use only.
- 2.2.2.3A Emergency equipment and medications must be secured with a disposable plastic lock.
 - i. Oxygen
 - must be inspected by authorized personnel every six months.
 - defibrillator/automated external defibrillator (AED)
 - testing and maintenance per the manufacturer’s specifications, must be documented.
- 2.2.3A Ultrasound imaging equipment:
 - 2.2.3.1A Must meet the IAC Vascular Testing or ACR Ultrasound Standards for equipment and must include:
 - i. color flow Doppler;
 - ii. imaging frequencies appropriate for the structures evaluated;
 - iii. Doppler frequencies appropriate for the vessel evaluated;
 - iv. range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest;
 - v. a Doppler angle which is measurable and adjustable;
 - vi. a visual display and capability of permanent recording of the image;
 - vii. a visual display, and audible output, and capability for a permanent recording of the Doppler waveform and corresponding image which includes Doppler angle.
- 2.2.4A Required supplies must include, but are not limited to:
 - 2.2.4.1A blood pressure cuff(s);
 - 2.2.4.2A stethoscope;
 - 2.2.4.3A flashlight/extra batteries;
 - 2.2.4.4A bag-valve-mask (AMBU) for resuscitation;
 - 2.2.4.5A oxygen;
 - 2.2.4.6A nasal cannula for oxygen administration;
 - 2.2.4.7A oxygen mask;
 - 2.2.4.8A nasal airway;
 - 2.2.4.9A needles and syringes.
- 2.2.5A Required minimum medication(s):
 - 2.2.5.1A Epinephrine 1:1000, 1 mL (2 ampules) OR Epi-Pen (pre-dosed) (2 pens);
 - 2.2.5.2A Diphenhydramine 50 mg/mL (2 ampules);

- 2.2.5.3A Diphenhydramine elixir/solution 12.5 mg/5 mL (1 bottle) *(optional)*;
 - 2.2.5.4A Diphenhydramine HCl 25,50 mg caps (1 bottle of each) *(optional)*;
 - 2.2.5.5A Methylprednisolone 125 mg (2 vials);
 - 2.2.5.6A Aspirin (325 mg, uncoated);
 - 2.2.5.7A Intravenous solutions and supplies *(optional)*.
- 2.2.6A If moderate/IV sedation or greater is utilized local/state guidelines must be followed. In the absence of such guidelines, American Society of Anesthesiologists (ASA) guidelines are recommended. At a minimum the following monitoring equipment must be available:
- 2.2.6.1A noninvasive blood pressure;
 - 2.2.6.2A pulse oximetry;
 - 2.2.6.3A ECG monitoring.
- 2.2.7A Sterilization of medical instruments:
- 2.2.7.1A The reuse of an FDA-approved single use device is not permitted.
 - 2.2.7.2A Single use products must be used prior to expiration date.
 - 2.2.7.3A Products approved by the FDA for multiple use must be re-sterilized by the process approved by the FDA or Center for Disease Control (CDC), as applicable.
 - 2.2.7.4A If performed on site, the facility must have a written protocol for sterilization of reusable medical instruments.
 - i. The policy must include, but is not limited to:
 - comprehensive training for all staff assigned;
 - reprocessing instructions (provided by the instrument/sterilization manufacturer);
 - sterilizer maintenance as needed with records of service;
 - a system of process monitoring;
 - visual inspection of packaging materials including heat sensitive indicators inside each package treated with steam sterilization;
 - results of periodic biological monitoring performed at least weekly;
 - retainment of sterilization records for a time period that complies with the CDC standards (e.g., three years), statutes of limitations and state and federal regulations;
 - an established blood borne pathogen exposure control plan in accordance with OSHA Bloodborne Pathogens Standards and must use universal precautions.

Section 3A: Administrative

STANDARD – Patient Confidentiality

- 3.1A 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

- 3.2A 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

- 3.3A 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

- 3.4A All medical records must be retained in accordance with applicable state or federal guidelines for medical records, generally five to seven years.

Bibliography

1. American Society of Anesthesiologists (ASA) Standards, Guidelines and Statements.
www.asahq.org/standards-and-guidelines
2. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H. and the Healthcare Infection Control Practices Advisory Committee (HICPAC).
www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
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

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

- 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 section 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. femoral vein mid thigh;
 - vi. popliteal vein;
 - vii. anterior accessory saphenous vein (when identified);
 - viii. small saphenous vein at saphenopopliteal junction if visualized; if not visualized there, the small saphenous vein at the proximal calf must be documented.
 - ix. perforator vein waveforms in the setting of active or healed venous ulcers, as required by the protocol;
 - x. 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;
 - iv. anterior accessory saphenous vein (when identified);

- v. small saphenous vein at saphenopopliteal junction if visualized; if not visualized there, the small saphenous vein at the proximal 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-specific informed consent
 - 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 a summary of the procedure;
 - i. Documentation may be facilitated by recording a diagram of the extremity treated.
 - 1.4.1.2B any immediate complications or adverse events;
 - 1.4.1.3B the patient's status at the end of the procedure;
 - 1.4.1.4B total volume of sclerosants(s);
 - 1.4.1.5B sclerosant concentration(s);
 - 1.4.1.6B ultrasound-guidance (if used);
 - 1.4.1.7B veins treated (spider, reticular, varicose tributaries, great saphenous, small saphenous, perforator, etc.);
 - 1.4.1.8B 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 outcomes.

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

- 1.5.2.1B allergic reactions;
- 1.5.2.2B deep vein thrombosis;
- 1.5.2.3B extension of thrombus into the deep veins, Endovenous Heat Induced Thrombus (EHIT);
- 1.5.2.4B skin burns and parasthesias;
- 1.5.2.5B 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;
- 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 Multiuse vials must be marked with the drug name, concentration, date of creation, initials of who made it and expiration date.
 - i. A new needle and syringe must be used for every entry into the vial.
 - ii. The vial stopper must be disinfected with an alcohol swab or equivalent antiseptic prior to entry.
 - iii. To avoid contamination, venting needles or other objects may not be left in the stopper.
- 1.6.1.3B 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 During the Performance of the Procedure:
 - 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 Sclerotherapy Procedure-Specific Documentation:
 - 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 **Ambulatory Phlebectomy:**
 - 1.7.1B Prior to Performance of the Procedure:
 - 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 Ultrasound imaging equipment or transillumination device, as defined by the procedure.
 - 1.7.1.5B Varicose veins must be marked immediately prior to the procedure.
 - 1.7.1.6B Sterile prep of the treatment area.

- 1.7.2B During the Performance of the Procedure:
 - 1.7.2.1B Appropriate ambulatory phlebectomy technique using hemostatic compression.
- 1.7.3B Ambulatory Phlebectomy Procedure-Specific Documentation:
 - 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.
 - 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;
- 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

1.10.1B **Prior to Performance of the Procedure:**

1.10.1.1B Appropriate supplies as defined by the procedure:

- i. wound care, debridement and dressing supplies;
- ii. compression;
- iii. therapeutic support stockings and other compression devices.

1.10.1.2B Appropriate pharmacologic agents.

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.

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 75 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

Selected Bibliography

1. Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: An Updated Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology*, 2002;96:1004-17. anesthesiology.pubs.asahq.org/article.aspx?articleid=1944958
2. 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
3. Medical issues and emergencies in the dermatology office. Fader, D., et al, *J Am Acad Dermatol*, 1997; 36(1):1-18. [www.jaad.org/article/S0190-9622\(97\)70319-0/fulltext](http://www.jaad.org/article/S0190-9622(97)70319-0/fulltext)
4. Medical Emergency Preparedness in Office Practice. Toback, S. *Am Fam Physician*, 2007; 75(11):1679-84. www.aafp.org/afp/2007/0601/p1679.html
5. Quality Improvement Guidelines for Preventing Wrong Site, Wrong Procedure, and Wrong Person Errors: Application of the Joint Commission “Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery” to the Practice of Interventional Radiology. Angle, J., et al, *J Vasc Interv Radiol*, 2008; 19:1145-1151. [www.jvir.org/article/S1051-0443\(08\)00473-9/fulltext](http://www.jvir.org/article/S1051-0443(08)00473-9/fulltext)
6. Multi-society Consensus Quality Improvement Guidelines for the Treatment of Lower-extremity Superficial Venous Insufficiency with Endovenous Thermal Ablation from the Society of Interventional Radiology, Cardiovascular Interventional Radiological Society of Europe, American College of Phlebology, and Canadian Interventional Radiology Association. Khilnani, N., et al, *J Vasc Interv Radiol*, 2010;21(1):14-31. [www.jvir.org/article/S1051-0443\(09\)00131-6/fulltext](http://www.jvir.org/article/S1051-0443(09)00131-6/fulltext)
7. Fluoro Quality Assurance Guide (IAC Vein Center). intersocietal.org/document/fluoro-quality-assurance-guide

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 appropriateness;
 - 1.1.2C technical performance of the procedure;
 - 1.1.3C patient safety;
 - 1.1.4C procedure outcomes including complications and any adverse event (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.

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.

2.1.1C Procedure Appropriateness

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

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

2.1.1.2C Appropriate indications for the procedures must be measured for consecutive cases over a time period which results in no less than 5% of the annual volume of cases.

- i. For smaller volume facilities, a minimum of 30 cases must be reviewed.

2.1.2C Technical 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 the diagnostic ultrasound;

2.1.2.5C reflux Doppler measurement;

2.1.2.6C diameter measurements;

2.1.2.7C 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 Medical Record Completeness and Timeliness:

2.1.4.1C Time from completion of procedure to signature of final documentation completed within two weeks.

2.1.5C Procedure Outcomes

2.1.5.1C 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.

2.1.5.2C Must document all procedural outcomes in the patient medical record.

2.1.5.3C Must document all adverse events that occur within (30 days) post-procedure in a centralized location or in retrievable electronic medical records for review (download the Vein Center Procedure Complications list at intersocietal.org/document/vein-procedure-complication-list).

2.1.5.4C Review of each case requiring referral outside the center for treatment of complications.

[\(See Guidelines on Page 32 for further recommendations.\)](#)

Section 2C: Quality Improvement Measures *Guidelines*

2.1C *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.

Selected Bibliography

1. The 2020 Appropriate Use Criteria for Chronic Lower Extremity Venous Disease of the American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology. Masuda, E., et al, *Journal of Vascular Surgery Venous and Lymphatic Disorders*, 2020 8(1): 505-524. www.jvsvenous.org/action/showPdf?pii=S2213-333X%2820%2930094-9

Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

- 3.1C The facility must have a minimum of two QI meetings per year, one of which is to review the results of the QI analyses.
 - 3.1.1C Every significant complication must be reviewed during these meetings any additional QI-related topics.
 - 3.1.2C All clinical staff must participate in at least one meeting per year.

Section 4C: Quality Improvement Documentation

STANDARD – QI Documentation

4.1C QI Documentation and Record Retention

4.1.1C The facility QI documentation must include but is not limited to:

4.1.1.1C the data for all of the QI measures;

4.1.1.2C changes in procedures or policies as a result of this analysis;

4.1.1.3C minutes from the QI meetings; and

4.1.1.4C participant list (may include remote participation and/or review of minutes).

4.1.2C The QI documentation must be maintained and available for all appropriate personnel to review.

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 Cardiovascular Angiography and Interventions (SCAI) - www.scai.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 Surgery (SVS) - vascular.org
- Society for Vascular Ultrasound (SVU) - www.svunet.org
- Society of Interventional Radiology (SIR) - www.sirweb.org