The Complete

ICAVL STANDARDS FOR ACCREDITATION IN NONINVASIVE VASCULAR TESTING

Parts I through VII
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4/10 ICAVL Standards 2
PART I
Organization

SECTION 1:
Supervision and Personnel

Introduction: A vascular laboratory is a unit performing noninvasive vascular diagnostic testing under the overall direction of a Medical Director. A Technical Director is appointed who is responsible for the direct supervision of all the technical staff and the daily operations of the laboratory. All interpreting physicians (medical staff) and practicing technologists (technical staff) must be adequately trained and experienced to interpret and perform noninvasive vascular testing respectively.

In addition to all standards listed below, the laboratory, 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.

STANDARD – Medical Director

1. A qualified Medical Director must be designated for the facility.

1.1 Responsibilities include but are not limited to:

1.1.1 All clinical services provided and the quality and appropriateness of the care provided

1.1.2 Supervises the entire operation; may delegate specific duties to appropriate staff

1.1.3 Approval of the medical staff and supervision of their work

1.1.4 Maintaining and assuring compliance to the standards as outlined in this document

Comment: If the Medical Director is off site, he/she must have a physical presence in the lab to participate in regular QA meetings, case study review conferences, personnel interviews and other laboratory operations.

1.1.2 Medical Director qualifications:

1.1.2.1 Must be a licensed physician

1.1.2.2 Licensed in the state or jurisdiction of the laboratory

1.1.2.3 Must be qualified to interpret noninvasive vascular examinations

1.1.3 Training and experience requirements

The Medical Director must demonstrate an appropriate level of training and experience by meeting one or more of the following:
1.1.3.1 Formal training

Completion of a residency or fellowship that includes appropriate didactic and clinical vascular laboratory experience as an integral part of the program. For those testing areas in which training is provided, the physician must have experience in interpreting the following minimum number of diagnostic studies under supervision:

- Carotid duplex ultrasound – 100 cases
- Transcranial Doppler – 100 cases
- Peripheral arterial physiologic – 100 cases
- Peripheral arterial duplex – 100 cases
- Venous duplex ultrasound – 100 cases
- Visceral vascular duplex ultrasound – 75 cases

1.1.3.2 Informal training

Appropriate training and experience for proper qualifications to interpret noninvasive vascular laboratory studies can be achieved through formal accredited post graduate education.

1.1.3.2.1 A minimum of 40 hours of relevant Category 1 CME credits must be acquired within the three-year period prior to the initial application.

- Twenty (20) hours must be courses specifically designed to provide knowledge of the techniques, limitations, accuracies and methods of interpretations of noninvasive vascular laboratory examinations the physician will interpret.
- Twenty (20) hours may be dedicated to appropriate clinical topics relevant to vascular testing.
- Eight (8) of the 40 hours must be specific to each testing area the physician will interpret.

1.1.3.2.2 The physician must acquire a minimum of 8 hours supervised practical experience for each testing area to be interpreted; observing or participating in testing procedures in an accredited laboratory.

Comment: Experience must be documented with a letter from the Medical Director of the laboratory where the experience was obtained.

1.1.3.2.3 For those examinations the physician will interpret, there must be documentation of interpretation for the following minimum number of studies while under the supervision of a physician who has already met the ICAVL Standard.

- Carotid duplex ultrasound – 100 cases
- Transcranial Doppler – 100 cases
- Peripheral arterial physiologic – 100 cases
- Peripheral arterial duplex – 100 cases
- Venous duplex ultrasound – 100 cases
- Visceral vascular duplex ultrasound – 75 cases
1.1.3.3 Established practice

Current training and current experience will be considered appropriate for a physician who has met the qualifications of and has worked in a vascular laboratory for at least the past three years and has interpreted the following minimum number of diagnostic studies in the specific areas that will be interpreted.

- Carotid duplex ultrasound – 300 cases
- Transcranial Doppler – 300 cases
- Peripheral arterial physiologic – 300 cases
- Peripheral arterial duplex – 300 cases
- Venous duplex ultrasound – 300 cases
- Visceral vascular duplex ultrasound – 225 cases

1.1.3.4 Physician credential for vascular interpretation

1.1.3.4.1 Registered Physician in Vascular Interpretation (RPVI)
1.1.3.4.2 Neurosonology credential (ASN) from the American Society of Neuroimaging (For physicians who interpret extracranial and intracranial examinations only.)

1.1.4 Continuing experience

1.1.4.1 The monthly volume must be sufficient to maintain proficiency in examination interpretation.

Comment: In general, the Medical Director should interpret a minimum of 5 noninvasive vascular examinations per month.

1.1.4.2 The total volume of interpretations may be combined from sources other than the applicant laboratory.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.

1.1.5 Continuing medical education (CME)

The Medical Director must show evidence for maintaining current knowledge by participating in CME courses that are relevant to vascular testing. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.

1.1.5.1 A minimum of 15 hours of CME is required every three years, of which 10 hours must be Category 1.

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

1.1.5.2 The CME requirement will be waived if, in the previous three years prior to the application submission, the Medical Director has:

- Completed formal training
- Acquired an appropriate vascular credential
- Been employed in the laboratory less than one year
STANDARD – Technical Director

1.2 A qualified Technical Director must be designated for the facility.

1.2.1 The Technical Director is generally a full-time position.

1.2.1.1 If the Technical Director is not onsite full time, he/she must work a minimum of 20% of normal business hours each month AND

1.2.1.2 An appropriately credentialed technologist must be appointed in the Technical Director’s absence and report to the Technical Director.

The appointed technologist must:

- Supervise and assist others in performing the examinations
- Oversee day to day operations
- Communicate weekly with the Technical Director to maintain compliance with the standards.

Comment: The Medical Director or a member of the medical staff must satisfy the qualifications of the Technical Director to serve in that capacity.

1.2.2 Technical Director responsibilities include but are not limited to:

1.2.2.1 Must report directly to the Medical Director

1.2.2.2 All laboratory duties as delegated by the Medical Director

1.2.2.3 Supervision of the technical and ancillary staff (may be delegated)

1.2.2.4 Daily technical operation of the laboratory: staffing, scheduling, record keeping

1.2.2.5 Quality patient care

1.2.2.6 Technical training

1.2.2.7 Operation and maintenance of the equipment

1.2.2.8 Compliance to the standards as outlined in this document

1.2.3 Technical Director qualifications:

1.2.3.1 The Technical Director must have an appropriate credential in vascular testing.

1.2.3.1.1 Registered Vascular Technologist (RVT)

1.2.3.1.2 Registered Vascular Specialist (RVS)

1.2.3.1.3 Registered Technologist Vascular Sonography [RT(VS)]

1.2.3.1.4 Visceral vascular testing only: Registered Diagnostic Medical Sonographer in Abdomen [RDMS (AB)]

1.2.3.1.5 Physician technical directors for extracranial and/or intracranial testing only: Neurosonology credential (ASN) from the American Society of Neuroimaging
1.2.3.2 For each testing area applied for, the Technical Director must have performed the following minimum number of studies:

- Carotid duplex ultrasound – 100 cases
- Transcranial Doppler – 100 cases
- Peripheral arterial physiologic – 100 cases
- Peripheral arterial duplex – 100 cases
- Venous duplex ultrasound – 100 cases
- Visceral vascular duplex ultrasound – 75 cases

Comment: If the Technical Director does not meet the testing volume requirements for any testing section, a qualified co-technical director must be appointed for those testing sections.

1.2.4 Continuing experience

1.2.4.1 The monthly volume must be sufficient to maintain proficiency in examination performance.

Comment: In general, the Technical Director should perform a minimum of 5 noninvasive vascular examinations per month.

1.2.4.2 The total volume of cases may be combined from sources other than the applicant laboratory.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.

1.2.5 Continuing medical education

The Technical Director must show evidence of maintaining current knowledge by participating in CME courses that are relevant to vascular testing. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.

1.2.5.1 A minimum of 15 hours of CME is required every three years.

1.2.5.2 At least one hour of the 15 CME should be relative to work related musculoskeletal disorders (MSD).

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

1.2.5.3 The CME requirement will be waived if, in the previous three years prior to the application submission, the Technical Director has:

- Completed formal training
- Acquired an appropriate vascular credential
- Been employed in the laboratory less than one year
STANDARD – Medical Staff

1.3  A qualified medical staff must be designated for the facility.

1.3.1  Medical staff responsibilities include but are not limited to:

1.3.1.1  The medical staff interprets and/or performs clinical studies in accordance with privileges approved by the Medical Director and in compliance with the standards outlined in this document.

1.3.2  Medical staff qualifications:

1.3.2.1  Must be a licensed physician

1.3.2.2  Must be qualified to interpret noninvasive vascular examinations

1.3.3  Training and experience requirements

The medical staff must demonstrate an appropriate level of training and experience by meeting one or more of the following:

1.3.3.1  Formal training

Completion of a residency or fellowship that includes appropriate didactic and clinical vascular laboratory experience as an integral part of the program. For those testing areas in which training is provided, the physician must have experience in interpreting the following minimum number of diagnostic studies under supervision:

- Carotid duplex ultrasound – 100 cases
- Transcranial Doppler – 100 cases
- Peripheral arterial physiologic – 100 cases
- Peripheral arterial duplex – 100 cases
- Venous duplex ultrasound – 100 cases
- Visceral vascular duplex ultrasound – 75 cases

1.3.3.2  Informal training

Appropriate training and experience for proper qualifications to interpret noninvasive vascular laboratory studies can be achieved through formal accredited post graduate education.

1.3.3.2.1  A minimum of 40 hours of relevant Category 1 CME credits must be acquired within the three-year period prior to the initial application.
  - Twenty (20) hours must be courses specifically designed to provide knowledge of the techniques, limitations, accuracies and methods of interpretations of noninvasive vascular laboratory examinations the physician will interpret.
  - Twenty (20) hours may be dedicated to appropriate clinical topics relevant to vascular testing.
  - Eight (8) of the 40 hours must be specific to each testing area the physician will interpret.

1.3.3.2.2  The physician must acquire a minimum of 8 hours supervised practical experience for each testing area to be interpreted; observing or participating in testing procedures in an accredited laboratory.
Comment: Experience must be documented with a letter from the Medical Director of the laboratory where the experience was obtained.

1.3.3.2.3 For those examinations the physician will interpret, there must be documentation of interpretation for the following minimum number of studies while under the supervision of a physician who has already met the ICAVL criteria.

- Carotid duplex ultrasound – 100 cases
- Transcranial Doppler – 100 cases
- Peripheral arterial physiologic – 100 cases
- Peripheral arterial duplex – 100 cases
- Venous duplex ultrasound – 100 cases
- Visceral vascular duplex ultrasound – 75 cases

1.3.3 Established practice

Current training and current experience will be considered appropriate for a physician who has met the qualifications and has worked in a vascular laboratory for at least the past three years and has interpreted the following minimum number of diagnostic studies in the specific areas that will be interpreted.

- Carotid duplex ultrasound – 300 cases
- Transcranial Doppler – 300 cases
- Peripheral arterial physiologic – 300 cases
- Peripheral arterial duplex – 300 cases
- Venous duplex ultrasound – 300 cases
- Visceral vascular duplex ultrasound – 225 cases

1.3.3.4 Physician credential for vascular interpretation

1.3.3.4.1 Registered Physician in Vascular Interpretation (RPVI)
1.3.3.4.2 Neurosonology credential (ASN) from the American Society of Neuroimaging (For physicians who interpret extracranial and intracranial examinations only.)

1.3.4 Continuing experience

1.3.4.1 The monthly volume must be sufficient to maintain proficiency in examination interpretation.

Comment: In general, all medical staff members should interpret a minimum of 5 noninvasive vascular examinations per month.

1.3.4.2 The total volume of interpretations may be combined from sources other than the applicant laboratory.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.
1.3.5 Continuing medical education

Each medical staff member must show evidence of maintaining current knowledge by participating in CME courses that are relevant to vascular testing. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.

1.3.5.1 A minimum of 15 hours of CME is required every three years, of which 10 hours must be Category 1.

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

1.3.5.2 The CME requirement will be waived if, in the previous three years prior to the application submission, the medical staff member has:

- Completed formal training
- Acquired an appropriate vascular credential
- Been employed in the laboratory less than one year

STANDARD – Technical Staff

1.4 A qualified technical staff must be designated for the facility.

1.4.1 Responsibilities include but are not limited to:

1.4.1.1 Reports to the Technical Director

1.4.1.2 Performance of clinical examinations and other assigned tasks

1.4.2 Technical staff qualifications

The technical staff must have an appropriate level of training and experience by meeting one or more of the following criteria:

Comment: Though the standards include multiple pathways by which a technical staff member may document experience and training, the ICAVL encourages that all staff members acquire an appropriate credential in vascular testing.

(Note: By January 2017, all technical staff must have obtained an appropriate credential in vascular testing.)

1.4.2.1 Credential: An appropriate credential in vascular testing

1.4.2.2 Formal ultrasound training: Successful completion of a diagnostic ultrasound or cardiovascular technology program with a concentration in vascular technology.

1.4.2.2.1 The program should be accredited by the Commission for Accreditation of Allied Health Education Programs (CAAHEP) in collaboration with the Joint Review Committee on Education in Diagnostic Medical Sonography (JRC-DMS) and/or the Joint Review Committee on Education in Cardiovascular Technology (JRC-CVT) or the Canadian Medical Association (CMA).
1.4.2.3 Post secondary education plus 12 months full time (at least 35 hours per week) clinical vascular testing experience plus one of the following:

1.4.2.3.1 Completion of a formal two-year program or equivalent in another allied health profession
1.4.2.3.2 Completion of a bachelor’s degree unrelated to vascular technology
1.4.2.3.3 A MD or DO degree

1.4.2.4 Experience only

1.4.2.4.1 A minimum of 12 months of vascular testing experience with the performance of at least 600 noninvasive vascular examinations under the supervision of medical or technical staff who meet one of the above criteria.
1.4.2.4.2 These examinations must be appropriately distributed among the testing areas performed in the laboratory.

Comment: An individual who does not meet one of the above is considered a trainee.

1.4.3 For each testing area applied for, the technical staff member must have performed the following minimum number of studies:

- Carotid duplex ultrasound – 100 cases
- Transcranial Doppler – 100 cases
- Peripheral arterial physiologic – 100 cases
- Peripheral arterial duplex – 100 cases
- Venous duplex ultrasound – 100 cases
- Visceral vascular duplex ultrasound – 75 cases

Comment: An individual who does not meet the testing volume requirements for any testing section is considered a trainee.

1.4.4 Continuing experience

1.4.4.1 The monthly volume must be sufficient to maintain proficiency in examination performance.

Comment: In general, all technical staff members should perform a minimum of 5 noninvasive vascular examinations per month.

1.4.4.2 The total volume of cases may be combined from sources other than the applicant laboratory.

Comment: Lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant from applying for accreditation.

1.4.5 Continuing medical education

The technical staff must show evidence of maintaining current knowledge by participating in CME courses that are relevant to vascular testing. To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.
1.4.5.1 A minimum of 15 hours of CME is required every three years.

Comment: Laboratory internal quality assurance meetings are not eligible as part of this CME requirement.

1.4.5.2 The CME requirement will be waived if, in the previous three years prior to the application submission, the technical staff member has:

- Completed formal training
- Acquired an appropriate vascular credential
- Been employed in the laboratory less than one year

STANDARD – Trainees

1.5 Training if conducted must not compromise patient care and must benefit the trainee.

1.5.1 Trainee requirements:

1.5.1.1 Supervision: The Medical Director must ensure that the responsibilities assumed by the trainee are appropriate

1.5.1.2 Trainees must perform examinations only with direct medical and/or technical staff supervision.

STANDARD – Primary Source Verification

1.6 There must be a policy in place identifying how the laboratory/facility verifies the medical education, training, appropriate licenses and certifications of all physicians as well as, the certification and training of all technical staff members and any other direct patient care providers.
SECTION 2:
Support Services

STANDARD – Support Services

2.1 Ancillary personnel (clerical, nursing, transport, etc.) necessary for safe and efficient patient care must be provided.

2.1.1 Requirements:

2.1.1.1 The Medical Director must ensure that support services are appropriate and in the best interest of patient care.

2.1.1.2 Clerical and administrative support must be sufficient to ensure efficient laboratory operational record keeping.

2.1.1.3 Nursing and ancillary services must be sufficient to ensure quality patient care.

SECTION 3:
Physical Facilities

STANDARD – Examination Areas

3.1 Examinations must be performed in a setting providing patient safety, comfort and privacy.

3.1.1 A policy must be in place to address technical staff safety, comfort and avoidance of work related musculoskeletal disorders (MSD).

Comment: For additional information regarding MSD, please visit:
- http://www.sdms.org/OSHA/etool.asp

STANDARD – Interpretation Space

3.2 Adequate designated space must be provided for the interpretation of examination results and preparation of reports.

STANDARD – Storage Space

3.3 Adequate designated space must be provided for the convenient storage of supplies, records and reports.
SECTION 4:  
Examination Interpretation, Reports and Records

STANDARD – Examination Interpretation and Reports

4.1 Noninvasive vascular examinations are interpreted and reported by the Medical Director or a member of the medical staff of the vascular laboratory.

Comment: The report represents the final interpretation of the noninvasive vascular examination and is part of the patient’s legal medical record. As such, the report must be in the form of a document that is retrievable and/or reproducible for review by health care personnel. In general, the report must contain information such that a health care professional previously unfamiliar with the case is provided adequate information regarding the indications for the examination, the type of examination performed and the results of the diagnostic study.

4.1.1 Requirements

4.1.1.1 All reporting must be standardized.

4.1.1.2 All physicians interpreting noninvasive vascular examinations in the laboratory must agree on and utilize uniform diagnostic criteria and a standardized report format.

4.1.1.3 Interpretation must include review of all examination data including measurements, images and recordings by the Medical Director or a member of the medical staff.

4.1.1.4 The report must accurately reflect the content and results of the examination.

4.1.1.5 The final report must be verified and signed by the Medical Director or a member of the medical staff of the laboratory.

4.1.1.6 The final report must be typed and must include but is not limited to:

4.1.1.6.1 Date of the examination
4.1.1.6.2 Clinical indications leading to the performance of the examination
4.1.1.6.3 An adequate description of the examination performed and must include the name of the examination and its integral parts
4.1.1.6.4 Description of pertinent positive and negative findings
4.1.1.6.5 If disease is present it must be characterized according to its location, extent, severity and etiology whenever possible
4.1.1.6.6 Incidental findings
4.1.1.6.7 Reasons for a technically limited, suboptimal or incomplete examination
4.1.1.6.8 Summary (impression/conclusion) of the examination findings
4.1.1.6.9 The final interpretation should address the clinical indications for the examination.
4.1.1.6.10 Comparison with previous related studies when available
4.1.1.6.11 Interpreting physician typed name and signature and/or electronic verification

Comment: The use of a signature stamp is strongly discouraged. The use of the signature stamp provides the potential for inappropriate use by personnel other than the physician whose signature appears on the stamp.

4.1.1.6.12 Date of interpreting physician signature or verification
4.1.7 The interpretation by the Medical Director or a member of the medical staff must be available within two (2) working days of the examination.

Comment: An interpretation can be in the form of paper, digital storage or voice system. The final verified signed report must be available in a timely fashion, generally within four (4) business days.

4.1.8 Identification of the technologist performing the examination must appear as part of the permanent record.

4.1.9 If preliminary findings are provided, the preliminary nature must be clearly indicated.

4.1.9.1 A mechanism for communication of any significant changes must be defined for those situations in which the final interpretation differs substantially from the preliminary findings.

4.1.10 A mechanism must be defined whereby the results of the examination that demonstrate urgent or life threatening findings are communicated to the appropriate health care professionals in a timely fashion.

STANDARD – Records

4.2 Provisions exist for the generation and retention of examination records of all studies performed.

4.2.1 Requirements

4.2.1.1 Essential portions of all examinations must be documented on media appropriate for long-term storage.

Comment: Final submission of representative case studies to the ICAVL must be in a digital format (e.g., CD, DVD or flash drive; no videotape recordings will be accepted).

4.2.2 A complete, accurate and signed final report must be generated as outlined in SECTION 4: Examination Interpretation, Reports and Records, as part of the record of examination.

4.2.3 All records of the examination, including a signed dated final report must be retained in accordance with applicable state or federal guidelines for medical records, generally five to seven years for adult patients.
SECTION 5: 
Patient Safety and Confidentiality

STANDARD – Patient Safety

5.1. Patient safety must be ensured by written policies and procedures approved by the Medical Director.

5.1.1. A written procedure must be documented for identification of patients who suffer untoward effects or complications of studies performed and a permanent record of such is maintained.

5.1.2. A written procedure must be documented with respect to:

5.1.2.1. Control of infectious disease

5.1.2.2. Transducer cleaning

5.1.2.3. Protection of laboratory personnel from the transmission of infectious disease and blood borne pathogens

5.1.3. Written procedures must be documented for handling acute medical emergencies and critically ill patients that includes:

5.1.3.1. Appropriate equipment

5.1.3.2. Supplies

5.1.3.3. Trained personnel

5.1.4. The laboratory must meet the standards as set forth by the Occupational Safety and Health Administration (OSHA) and the Joint Commission (JC) where applicable.

STANDARD – Patient Confidentiality

5.2. All laboratory personnel must ascribe to professional principles of patient – physician confidentiality as legally required by federal, state, local or institutional policy or regulation.

STANDARD – Patient or Other Customer Complaints

5.3. 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 laboratory/facility and how the facility handles complaints/grievances.
SECTION 6:
Multiple Sites (Fixed and/or Mobile)

STANDARD – Multiple Sites

6.1 When testing is performed at more than one physical facility, the laboratory may be eligible to apply for a single accreditation as a multiple site laboratory.

6.1.1 All facilities must have the same Medical Director.

6.1.2 All facilities must have the same Technical Director.

6.1.3 Supervision must be accomplished by one or more of the following:

6.1.3.1 The Technical Director works at each site two days per month.

6.1.3.2 Every technical staff member from each multisite works at the main laboratory two days each month.

6.1.3.3 An appropriately credentialed lead technologist is appointed at each multisite laboratory and reports to the Technical Director.

6.1.3.3.1 The lead technologist must:

- Supervise and assist other technical staff members in performing examinations.
- Oversee the daily activities of the multisite.
- Communicate weekly with the Technical Director to maintain compliance with these standards.

6.1.4 Identical examination protocols must be utilized at all sites.

6.1.5 Identical diagnostic criteria must be utilized at all sites.

6.1.6 Quality assurance must be performed at each site for all applicable testing areas.

6.1.7 Equipment of similar quality and capability must be utilized at all sites.
PART II:
Vascular Laboratory Testing –
Extracranial Cerebrovascular

STANDARD – Indications

1.1 Extracranial cerebrovascular testing must be performed for appropriate clinical indications

1.1.1 The indication for testing must be documented prior to performing the examination.

1.1.2 When available, appropriateness criteria published by medical professional organizations should be utilized.

Comment: An accepted indication is generally written by the referring health-care provider. In some instances it can only be assessed at the time of the examination.

STANDARD – Equipment

2.1 Equipment must provide accurate data.

2.1.1 Imaging equipment – Duplex ultrasound with color flow Doppler must be provided with:

2.1.1.1 Imaging frequencies appropriate for the structures evaluated.

2.1.1.2 Doppler frequencies appropriate for the vessels evaluated.

2.1.1.3 Range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest.

2.1.1.4 A Doppler angle which is measurable and adjustable.

2.1.1.5 A visual display and a permanent recording of the image.

2.1.1.6 A visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.

2.1.2 Equipment quality control

2.1.2.1 Equipment used for diagnostic testing must be maintained in good operating condition.

2.1.2.2 Equipment maintenance must include, but is not necessarily limited to:

2.1.2.2.1 Recording of the method and frequency of maintenance of all imaging equipment and non-imaging equipment.
2.1.2.2 Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.

2.1.2.3 Establishment of and adherence to an equipment cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to specifications of the manufacturer.

Comment: The cleaning schedule for each system will depend on the degree of use and should be frequent enough to allow for accurate collection of data.

STANDARD – Protocols

3.1 Each examination performed in the laboratory must have a written protocol. The protocol must include:

3.1.1 The equipment to be used for each examination.

3.1.2 The elements of proper technique (also see STANDARD – Techniques).

3.1.3 The anatomic extent that constitutes a complete examination.

3.1.3.1 Bilateral testing is considered an integral part of a complete examination.

3.1.3.2 Any variations in technique and documentation for examinations performed for the assessment of peripheral vascular interventions, including but not limited to sites of stenting, must be described.

3.1.3.3 Variations in technique and documentation for recurring limited examinations must be described.

Comment: A complete examination includes evaluation of the entire course of the accessible portions of each vessel. A limited examination is a subset of the complete examination. There may be recurring indications for a limited examination. The protocol should include the indications for a limited examination and the descriptions of the limited examination. Separate limited examination protocols may also be written.

3.1.4 The documentation that must be acquired for normal examinations and the additional documentation that must be acquired to describe abnormalities, if present (also see STANDARD – Documentation).

3.1.5 A description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement gray scale imaging, spectral Doppler and velocity measurements.
STANDARD – Techniques

4.1 Appropriate techniques must be used for the evaluation of the extracranial cerebrovascular system to assess for the presence of any abnormalities and to document their severity, location, extent and whenever possible etiology.

4.1.1 Elements of proper technique include, but are not limited to:

4.1.1.1 Performance of an examination according to the written, laboratory specific protocol.

4.1.1.2 Proper patient positioning.

4.1.1.3 Patient preparation, if appropriate.

4.1.1.4 Appropriate equipment selection and placement.

4.1.1.5 Optimization of equipment gain and display settings.

4.1.1.6 Appropriate transducer selection.

4.1.1.7 Proper sample volume size and positioning.

4.1.2 For imaging equipment, elements of proper technique include, but are not limited to:

4.1.2.1 A spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities.

4.1.2.2 Proper measurement of spectral velocities as required by the protocol.

4.1.2.3 Identification of vessels by imaging and Doppler.

STANDARD – Documentation

5.1 Each examination performed in the laboratory must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:

5.1.1 Gray scale images

5.1.2 Color Doppler images

5.1.3 Doppler waveforms

5.1.4 Velocity measurements

5.1.5 Other images and waveforms as required by the protocol

5.1.6 Other measurements as required by the protocol

5.2 For imaging equipment, abnormalities require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.
5.2.1 Documentation of areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.

5.2.2 Documentation of sites of peripheral vascular intervention, including but not limited to sites of stenting, must include representative Doppler waveforms and velocity measurements recorded from the proximal, mid and distal site.

5.3 Extracranial Cerebrovascular Documentation

5.3.1 Long axis gray scale images must be documented as required by the protocol and must include at a minimum:

- 5.3.1.1 Common carotid artery
- 5.3.1.2 Carotid artery bifurcation
- 5.3.1.3 Internal carotid artery

5.3.2 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- 5.3.2.1 Proximal common carotid artery
- 5.3.2.2 Mid/distal common carotid artery
- 5.3.2.3 Proximal internal carotid artery
- 5.3.2.4 Distal internal carotid artery; as distal as possible
- 5.3.2.5 One site in the external carotid artery
- 5.3.2.6 One site in the vertebral artery

5.3.3 Abnormalities require additional images, waveforms and velocity measurements.

**STANDARD – Diagnostic Criteria**

6.1 Each examination performed in the laboratory must have a single set of written, validated diagnostic criteria to interpret the presence of disease and to document its severity, location, extent and whenever possible etiology.

6.1.1 Diagnostic criteria must be laboratory specific.

Comment: These criteria can be based on published reports or internally generated and internally validated as outlined in STANDARD – Quality Assurance.

6.1.2 For imaging equipment, for each examination performed there must be diagnostic criteria for the interpretation of:

- 6.1.2.1 Gray scale images
  - 6.1.2.1.1 Plaque morphology, when utilized
6.1.2.2 Spectral Doppler waveforms
6.1.2.3 Spectral Doppler velocities
6.1.2.4 Color Doppler images (if used)
6.1.2.5 Other imaging modes (if used)

6.1.3 When interpreted, there must be diagnostic criteria for the interpretation of:

6.1.3.1 Internal carotid artery (ICA) stenosis/disease: These criteria must state how velocity measurements, spectral Doppler waveform analysis and imaging are used to document the severity, location, extent and whenever possible etiology.

6.1.3.2 Common carotid artery (CCA) and external carotid artery (ECA) disease: These criteria must state how velocity measurements, spectral Doppler waveform analysis and imaging are used to document the severity, location, extent and whenever possible etiology.

Comment: Criteria for CCA and ECA stenosis have not been validated as extensively as for the ICA and generally the grades of stenosis for these vessels are more broad (e.g., normal, less than 50% diameter reduction, greater than 50% diameter reduction, occlusion).

6.1.3.3 Vertebral artery disease:

At a minimum, these criteria must state how velocity measurements, spectral Doppler waveform analysis and imaging are used to document steal physiology.

STANDARD – Interpretation

7.1 Interpretation using the documented findings and the diagnostic criteria must be performed by the Medical Director or a member of the medical staff to indicate the absence or presence of abnormalities in the sites and vessels that were examined.

7.1.1 Disease, if present, must be characterized according to:

7.1.1.1 Severity

7.1.1.2 Location

7.1.1.3 Extent

7.1.1.4 Etiology whenever possible

Comment: For the requirements of interpretation/final report, refer to SECTION 4 – Examination Interpretation, Reports and Records in Part I: Organization.
STANDARD – Quality Assurance

8.1 Quality assurance must be performed.

8.1.1 There must be a written policy regarding quality assurance for all procedures performed in the laboratory.

8.1.2 Results of extracranial cerebrovascular examinations must be regularly correlated with other imaging modalities, preferably angiographic and/or surgical findings as described below.

8.1.2.1 The laboratory must have a written procedure for regular correlation of the extracranial cerebrovascular examinations with angiographic findings produced by digital subtraction angiography, contrast enhanced computed tomography, magnetic resonance angiography or operative findings.

8.1.2.2 The correlation must be reported using the comparison of the results of the extracranial cerebrovascular examination and the results of the validating study with regard to the location and severity of the disease as defined by the diagnostic criteria utilized by the laboratory.

8.1.2.3 A minimum of 30 internal carotid arteries must be correlated

Comment: The time interval between the vascular laboratory examination and the correlative study for quality assurance purposes should be appropriate for the disease being correlated. For diseases which may change rapidly (e.g., vasospasm), a short time interval is appropriate. For diseases which generally change more slowly (e.g., atherosclerosis) and where there has been no change in signs or symptoms, a longer interval is acceptable. Many current clinical trials of atherosclerotic disease accept a 90-120 day interval between an imaging study and enrollment. Confirmation of a normal vessel also may have a longer interval before correlation is performed. If the patient’s signs or symptoms change in the interval between the vascular laboratory examination and the correlative study, comparison of these studies is not an acceptable quality assurance mechanism.

8.1.2.4 The correlation log must demonstrate greater than 70% accuracy agreement.

8.1.2.5 Documentation of correlation must be maintained.

Comment: The correlations submitted must have been completed within the three years preceding submission of the application. If the laboratory is unable to obtain the minimum number of correlations, alternative methods for QA may be considered on an individual laboratory basis. The laboratory must submit the written plan of action for documentation of ongoing quality measures to assess the accuracy of examinations.

8.1.3 Quality assurance meetings

8.1.3.1 A minimum of two vascular laboratory quality assurance meetings per year must be held to:

8.1.3.1.1 Review the results of comparative studies
8.1.3.1.2 Address discrepancies
8.1.3.1.3 Discuss difficult cases
8.1.3.1.4 Address laboratory quality assurance issues

8.1.3.2 Minutes of the quality assurance meetings must be maintained.
STANDARD – Procedure Volumes

9.1   The annual procedure volume must be sufficient to maintain proficiency in examination techniques and interpretation.

Comment: In general, a laboratory should perform a minimum of 100 complete examinations annually.

9.1.1   Records must be maintained that permit evaluation of annual procedure volumes. These records must include:

9.1.1.1   The indication for the examination

9.1.1.2   The technologist performing the examination

9.1.1.3   The examination(s) performed

9.1.1.4   The examination findings

9.1.1.5   The physician interpreting the examination
PART III:
Vascular Laboratory Testing –
Intracranial Cerebrovascular

STANDARD – Indications

1.1 Intracranial cerebrovascular testing must be performed for appropriate clinical indications.

1.1.1 The indication for testing must be documented prior to performing the examination.

1.1.2 When available, appropriateness criteria published by medical professional organizations should be utilized.

Comment: An accepted indication is generally written by the referring health care provider. In some instances it can only be assessed at the time of the examination.

STANDARD – Equipment

2.1 Equipment must provide accurate data.

2.1.1 Imaging equipment – Duplex ultrasound with color flow Doppler, if used for testing, must be provided with:

2.1.1.1 Imaging frequencies appropriate for the structures evaluated.

2.1.1.2 Doppler frequencies appropriate for the vessels evaluated.

2.1.1.3 Range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest.

2.1.1.4 A Doppler angle which is measurable and adjustable.

2.1.1.5 A visual display and a permanent recording of the image.

2.1.1.6 A visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.

2.1.2 Continuous wave (CW) and pulsed wave (PW) Doppler, if used for testing, must be provided with:

2.1.2.1 A direction sensitive Doppler blood flow meter.

2.1.2.2 Doppler transducer frequencies appropriate for the vessels evaluated.

2.1.2.3 Doppler waveform display demonstrating bidirectional flow and signal intensity.

2.1.2.4 An audible output and a permanent recording of the waveform.
2.1.3 Automated software packages, if used for testing such as automated emboli detection or
calculators of hemodynamic indices, must be provided with:

2.1.3.1 Evidence of validation for the intended application.

2.1.4 Equipment quality control

2.1.4.1 Equipment used for diagnostic testing must be maintained in good operating condition.

2.1.4.2 Equipment maintenance must include, but is not necessarily limited to:

2.1.4.2.1 Recording of the method and frequency of maintenance of all imaging equipment and non-imaging equipment.

2.1.4.2.2 Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.

2.1.4.2.3 Establishment of and adherence to an equipment cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to specifications of the manufacturer.

Comment: The cleaning schedule for each system will depend on the degree of use and should be frequent enough to allow for accurate collection of data.

STANDARD – Protocols

3.1 Each examination performed in the laboratory must have a written protocol. The protocol must include:

3.1.1 The equipment to be used for each examination.

3.1.2 The elements of proper technique (also see STANDARD – Techniques).

3.1.3 The anatomic extent that constitutes a complete examination.

3.1.3.1 Bilateral evaluation of anterior and posterior circulations including flow detection via temporal, orbital (when appropriate), foraminal, and (when appropriate) submandibular windows must be described.

3.1.3.2 Any variations in technique and documentation for examinations performed for the assessment of peripheral vascular interventions, including but not limited to sites of stenting, must be described.

3.1.3.3 Variations in technique and documentation for recurring limited examinations must be described.

3.1.3.4 Separate written protocols for additional transcranial examinations, if performed, must include but may not be limited to:

3.1.3.4.1 Emboli detection
3.1.3.4.2 Vasomotor reactivity
3.1.3.4.3 Right-to-left shunt
3.1.3.4.4 Assessment of cerebral circulatory arrest
3.1.3.4.5 Peri-procedural or intra-operative monitoring
3.1.3.4.6 Monitoring of reperfusion therapies in acute stroke
3.1.3.4.7 Monitoring in the neuro-intensive care setting
Comment: A complete examination includes evaluation of the entire course of the accessible portions of each vessel. A limited examination is a subset of the complete examination. There may be recurring indications for a limited examination. The protocol should include the indications for a limited examination and the descriptions of the limited examination. Separate limited examination protocols may also be written.

3.1.4 The documentation that must be acquired for normal examinations and the additional documentation that must be acquired to describe abnormalities, if present (also see STANDARD – Documentation).

3.1.5 A description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement gray scale imaging, spectral Doppler and velocity measurements.

3.1.6 Depth ranges for each vessel segment in adults and children (when appropriate).

3.1.7 The extent of power reduction to be used for transorbital examinations.

3.1.7.1 For patient safety, the output power must not exceed 10% of maximum emitted power or 17 mW per cm² or equivalent measurements.

STANDARD – Techniques

4.1 Appropriate techniques must be used for the evaluation of the intracranial cerebrovascular system to assess for the presence of any abnormalities and to document their severity, location, extent and whenever possible etiology.

4.1.1 Elements of proper technique include, but are not limited to:

4.1.1.1 Performance of an examination according to the written, laboratory specific protocol.

4.1.1.2 Proper patient positioning.

4.1.1.3 Patient preparation, if appropriate.

4.1.1.4 Appropriate equipment selection and placement.

4.1.1.5 Optimization of equipment gain and display settings.

4.1.1.6 Appropriate transducer selection.

4.1.1.7 Proper sample volume size, depth and positioning.

4.1.2 For imaging equipment if used, elements of proper technique include, but are not limited to:

4.1.2.1 Spectral Doppler angle and placement as required by the protocol.

4.1.2.2 Proper measurement of spectral velocities as required by the protocol.

4.1.2.3 Identification of vessels by imaging and Doppler.

4.1.3 Headgear for monitoring transducer fixation should be used when appropriate.

4.1.4 Motion mode (M-mode) display may be used for window finding and vessel identification.
STANDARD – Documentation

5.1 Each examination performed in the laboratory must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:

5.1.1 Gray scale images (if imaging used)
5.1.2 Color Doppler images (if imaging used)
5.1.3 Doppler waveforms
5.1.4 Velocity measurements
5.1.5 Other images (if used) and waveforms as required by the protocol
5.1.6 Other measurements as required by the protocol

5.2 Abnormalities require additional images (if imaging used) and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.

5.2.1 Documentation of areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.

5.2.2 Documentation of sites of peripheral vascular intervention, including but not limited to sites of stenting, must include representative Doppler waveforms and velocity measurements recorded from the proximal, mid and distal site.

5.2.3 Intracranial cerebrovascular documentation

5.2.3.1 Spectral Doppler waveforms, velocity measurements, flow direction and signal intensity must be documented as required by the protocol and must include at a minimum the following segments:

5.2.3.1.1 Proximal M2 middle cerebral artery (MCA) / distal M1 MCA
5.2.3.1.2 Proximal M1 MCA
5.2.3.1.3 A1 anterior cerebral artery (ACA)
5.2.3.1.4 Cross-filling via anterior communicating artery (when detectable)
5.2.3.1.5 Terminal internal carotid artery (TICA)
5.2.3.1.6 Collateral flow via posterior communicating artery (when detectable)
5.2.3.1.7 P1 or P2 posterior cerebral artery (PCA)
5.2.3.1.8 Ophthalmic artery (when appropriate)
5.2.3.1.9 Internal carotid artery (ICA) siphon
5.2.3.1.10 Terminal vertebral artery (VA)
5.2.3.1.11 Proximal and distal basilar artery
5.2.3.1.12 Distal ICA segment at the entrance to the skull (when appropriate)

5.2.3.2 The laboratory should provide depth ranges for these segments in adults and children (when appropriate).
STANDARD – Diagnostic Criteria

6.1 Each examination performed in the laboratory must have a single set of written, validated diagnostic criteria to interpret the presence of disease and to document its location, extent, severity and whenever possible etiology.

6.2 Diagnostic criteria must be laboratory specific.

Comment: These criteria can be based on published reports or internally generated and internally validated as outlined in STANDARD – Quality Assurance.

6.2.1 For each examination performed there must be diagnostic criteria for the interpretation of:

- 6.2.1.1 Gray scale images (if used)
- 6.2.1.2 Spectral Doppler waveforms
- 6.2.1.3 Spectral Doppler velocities
- 6.2.1.4 Color Doppler images (if used)
- 6.2.1.5 Other imaging modes (if used)

STANDARD – Interpretation

7.1 Interpretation using the documented findings and the diagnostic criteria must be performed by the Medical Director or a member of the medical staff to indicate the absence or presence of abnormalities in the sites and vessels that were examined.

7.1.1 Disease, if present, must be characterized according to:

- 7.1.1.1 Location
- 7.1.1.2 Extent
- 7.1.1.3 Severity

7.1.1.4 Etiology whenever possible

Comment: For the requirements of interpretation/final report, refer to SECTION 4 – Examination Interpretation, Reports and Records in Part I: Organization.
STANDARD – Quality Assurance

8.1 Quality assurance must be performed.

8.1.1 There must be a written policy regarding quality assurance for all procedures performed in the lab.

8.1.2 Results of intracranial cerebrovascular examinations must be regularly correlated with other imaging modalities, preferably angiographic and/or surgical findings as described below.

8.1.2.1 The laboratory must have a written procedure for regular correlation of the intracranial cerebrovascular examinations with angiographic findings produced by digital subtraction angiography, contrast enhanced computed tomography, magnetic resonance angiography or operative findings or other appropriate correlative measure (i.e., echocardiography for shunts, clinical examination for brain death, etc).

8.1.2.2 The correlation must be reported using the comparison of the results of the intracranial cerebrovascular examination and the results of the validating study with regard to the location and severity of the disease as defined by the diagnostic criteria utilized by the laboratory.

8.1.2.3 A minimum of 30 separate examinations, including normal and abnormal intracranial studies, must be correlated every three years. A minimum of 10 of the correlating studies must include abnormal intracranial findings.

Comment: The time interval between the vascular laboratory examination and the correlative study for quality assurance purposes should be appropriate for the disease being correlated. For diseases which may change rapidly (e.g., vasospasm), a short time interval is appropriate. For diseases which generally change more slowly (e.g., atherosclerosis) and where there has been no change in signs or symptoms, a longer interval is acceptable. Many current clinical trials of atherosclerotic disease accept a 90-120 day interval between an imaging study and enrollment. Confirmation of a normal vessel also may have a longer interval before correlation is performed. If the patient’s signs or symptoms change in the interval between the vascular laboratory examination and the correlative study, comparison of these studies is not an acceptable quality assurance mechanism.

8.1.2.4 The correlation log must demonstrate greater than 70% accuracy agreement.

8.1.2.5 Documentation of correlation must be maintained.

Comment: The correlations submitted must have been completed within the three years preceding submission of the application. If the laboratory is unable to obtain the minimum number of correlations, alternative methods for QA may be considered on an individual laboratory basis. The laboratory must submit the written plan of action for documentation of ongoing quality measures to assess the accuracy of examinations.

8.1.3 Quality assurance meetings

8.1.3.1 A minimum of two vascular laboratory quality assurance meetings per year must be held to:

8.1.3.1.1 Review the results of comparative studies
8.1.3.1.2 Address discrepancies
8.1.3.1.3 Discuss difficult cases
8.1.3.1.4 Address laboratory quality assurance issues

8.1.3.2 Minutes of the quality assurance meetings must be maintained.
STANDARD – Procedure Volumes

9.1 The annual procedure volume must be sufficient to maintain proficiency in examination techniques and interpretation.

Comment: In general, a laboratory should perform a minimum of 100 complete examinations annually.

9.1.1 Records must be maintained that permit evaluation of annual procedure volumes. These records must include:

9.1.1.1 The indication for the examination

9.1.1.2 The technologist performing the examination

9.1.1.3 The examination(s) performed

9.1.1.4 The examination findings

9.1.1.5 The physician interpreting the examination
PART IV:
Vascular Laboratory Testing –
Peripheral Arterial

STANDARD – Indications

1.1 Peripheral arterial testing must be performed for appropriate clinical indications.

1.1.1 The indication for testing must be documented prior to performing the examination.

1.1.2 When available, appropriateness criteria published by medical professional organizations should be utilized.

Comment: An accepted indication is generally written by the referring health care provider. In some instances it can only be assessed at the time of the examination.

STANDARD – Equipment

2.1 Equipment must provide accurate data.

2.1.1 Imaging equipment – Duplex ultrasound with color flow Doppler, if used for testing, must be provided with:

2.1.1.1 Imaging frequencies appropriate for the structures evaluated

2.1.1.2 Doppler frequencies appropriate for the vessels evaluated.

2.1.1.3 Range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest.

2.1.1.4 A Doppler angle which is measurable and adjustable.

2.1.1.5 A visual display and a permanent recording of the image.

2.1.1.6 A visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.

2.1.2 Continuous wave (CW) and pulsed wave (PW) Doppler, if used for testing, must be provided with:

2.1.2.1 A direction sensitive Doppler blood flow meter.

2.1.2.2 Doppler transducer frequencies appropriate for the vessels evaluated, which must be at least 3 MHz or greater.

2.1.2.3 Doppler waveform display demonstrating bidirectional flow.

2.1.2.4 An audible output and a permanent recording of the waveform.
2.1.3 Segmental limb plethysmography, if used for testing, must be provided with:

2.1.3.1 Equipment capable of measuring small segmental volume changes and providing permanent recordings.

2.1.3.2 Cuffs of varying sizes appropriate to the technique and the limb segment to be evaluated.

2.1.4 Supplemental equipment:

Comment: This equipment is inadequate to use alone to diagnose and grade the severity of disease.

2.1.4.1 Transcutaneous oximetry (TcPO2), if used for testing, must be provided with:

2.1.4.1.1 The capability of being calibrated before each examination.
2.1.4.1.2 An output expressed in mmHg.

2.1.4.2 Photoplethysmography (PPG), if used for testing, must be provided with:

2.1.4.2.1 Appropriate electrical coupling for signal display.
2.1.4.2.2 The capability of providing a permanent recording of the waveform.

2.1.4.3 Limb air plethysmography, if used for testing, must be provided with:

2.1.4.3.1 Appropriately sized pneumatic cuffs.
2.1.4.3.2 The capability of being calibrated before each examination.
2.1.4.3.3 The capability of measuring small limb volume changes.
2.1.4.3.4 The capability of providing a permanent recording of the data.

2.1.4.4 Laser Doppler, if used for testing, must be provided with:

2.1.4.4.1 Appropriate laser frequencies/laser diodes for transillumination of the skin.
2.1.4.4.2 Appropriate sized cuffs for coupling the probe to the limb segment.
2.1.4.4.3 The capability of providing a permanent recording of the data.

2.1.4.5 Treadmill exercise/stress testing, if used for testing, must be provided with:

2.1.4.5.1 Motor-driven treadmill capable of providing constant speed and inclination.

Comment: Other forms of standardized exercise may be utilized as defined by the laboratory protocol.

2.1.4.6 Automated software packages, if used for testing, must be provided with:

2.1.4.6.1 Evidence of validation for the intended application.

2.1.5 Equipment quality control

2.1.5.1 Equipment used for diagnostic testing must be maintained in good operating condition.

2.1.5.2 Equipment maintenance must include, but is not necessarily limited to:
2.1.5.2.1 Recording of the method and frequency of maintenance of all imaging equipment and non-imaging equipment.

2.1.5.2.2 Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.

2.1.5.2.3 Establishment of and adherence to an equipment cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to specifications of the manufacturer.

Comment: The cleaning schedule for each system will depend on the degree of use and should be frequent enough to allow for accurate collection of data.

STANDARD – Protocols

3.1 Each examination performed in the laboratory must have a written protocol. The protocol must include:

3.1.1 The equipment to be used for each examination.

3.1.2 The elements of proper technique (also see STANDARD – Techniques).

3.1.3 The anatomic extent that constitutes a complete examination.

3.1.3.1 Bilateral testing is considered an integral part of a complete examination.

3.1.3.2 Any variations in technique and documentation for examinations performed for the assessment of peripheral vascular interventions, including but not limited to sites of stenting, must be described.

3.1.3.3 Variations in technique and documentation for recurring limited examinations must be described.

Comment: A complete examination includes evaluation of the entire course of the accessible portions of each vessel. A limited examination is a subset of the complete examination. There may be recurring indications for a limited examination. The protocol should include the indications for a limited examination and the descriptions of the limited examination. Separate limited examination protocols may also be written.

3.1.4 The performance of an ankle brachial index (ABI).

3.1.5 The acquisition of waveforms (CW, PW or pulse volume recordings [PVR]) from at least three levels.

3.1.6 The measurement of systolic blood pressure at more than one level if indicated.

3.1.7 The documentation that must be acquired for normal examinations and the additional documentation that must be acquired to describe abnormalities, if present (also see STANDARD – Documentation).

3.1.8 A description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement gray scale imaging, spectral Doppler and velocity measurements.
STANDARD – Techniques

4.1 Appropriate techniques must be used for the evaluation of the peripheral arterial system to assess for the presence of any abnormalities and to document their severity, location, extent and whenever possible etiology.

4.1.1 Peripheral arterial examinations must include measurement of bilateral systolic blood pressures at one level at the ankle (or more if indicated) in combination with either Doppler or plethysmographic waveform analysis from at least three levels.

4.1.2 Peripheral arterial examinations must include performance of an ABI.

4.1.2.1 Measurement of upper extremity (brachial artery) systolic pressures must be obtained from both arms and the higher of the two pressures used to calculate the ABI.

4.1.2.2 Measurement of ankle systolic pressures must be obtained bilaterally from the distal posterior tibial (PT) artery and distal anterior tibial (AT)/dorsalis pedis (DP) artery and the higher of the two pressures on each side used to calculate the ABI.

4.1.2.3 Additional information regarding the presence of disease may be obtained by recording toe waveforms and toe systolic pressures, particularly in cases when the ABI may be non-diagnostic.

4.1.3 Elements of proper technique include, but are not limited to:

4.1.3.1 Performance of an examination according to the written, laboratory specific protocol.

4.1.3.2 Proper patient positioning.

4.1.3.3 Patient preparation, if appropriate.

Comment: For abdominal aorta testing, patient preparation may be necessary in order to minimize abdominal gas. This may include fasting and/or gas reducing medication.

4.1.3.4 Appropriate equipment selection and placement.

4.1.3.5 Optimization of equipment gain and display settings.

4.1.3.6 Appropriate transducer selection.

4.1.3.7 Proper sample volume size and positioning.

4.1.4 For imaging equipment if used, elements of proper technique include, but are not limited to:

4.1.4.1 A spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities.

4.1.4.2 Proper measurement of spectral velocities as required by the protocol.

4.1.4.3 Identification of vessels by imaging and Doppler.

Comment: Duplex ultrasound used to evaluate arteries and/or bypass grafts must include measurement and documentation of the ankle brachial indices that is generally performed at the time of the examination. Previous ABI measurements may only be used if...
• The ABI is performed within two weeks prior to the duplex examination AND
• was performed in the same laboratory AND
• there has been no change in the patient’s symptoms AND
• the results and date of the previous ABI must be included in the final report.

STANDARD – Documentation

5.1 Each examination performed in the laboratory must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:

5.1.1 Ankle brachial index (ABI).
   5.1.1.1 Bilateral brachial artery systolic pressures
   5.1.1.2 Bilateral ankle systolic pressures

5.1.2 Gray scale images (if used)

5.1.3 Color Doppler images (if used)

5.1.4 Doppler waveforms

5.1.5 Velocity measurements (if used)

5.1.6 Other images if used and waveforms as required by the protocol

5.1.7 Other measurements as required by the protocol

5.2 For imaging equipment, abnormalities require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.

5.2.1 Documentation of areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.

5.2.2 Documentation of sites of peripheral vascular intervention, including but not limited to sites of stenting, must include representative Doppler waveforms and velocity measurements recorded from the proximal, mid and distal site.

5.2.3 Duplex ultrasound of lower extremity arteries if performed must include:

   5.2.3.1 Gray scale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

   5.2.3.1.1 Common femoral artery
   5.2.3.1.2 Superficial femoral artery
   5.2.3.1.3 Proximal deep femoral artery
   5.2.3.1.4 Popliteal artery
   5.2.3.1.5 Aorta, common and external iliac arteries and tibial arteries when appropriate
   5.2.3.1.6 Bypass graft(s) when present including anastomoses
5.2.3.2 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum waveforms from:

5.2.3.2.1 Common femoral artery
5.2.3.2.2 Superficial femoral artery
5.2.3.2.3 Proximal deep femoral artery
5.2.3.2.4 Popliteal artery
5.2.3.2.5 Tibial arteries
5.2.3.2.6 Aorta, common and external iliac arteries when appropriate
5.2.3.2.7 Bypass graft when present, including proximal and distal anastomoses, inflow and outflow arteries

5.2.3.3 Abnormalities require additional images, waveforms and velocity measurements.

5.2.4 Duplex ultrasound of upper extremity arteries if performed must include:

5.2.4.1 Gray scale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

5.2.4.1.1 Subclavian artery
5.2.4.1.2 Axillary artery
5.2.4.1.3 Brachial artery
5.2.4.1.4 Innominate and forearm arteries when appropriate
5.2.4.1.5 Bypass graft(s) when present including anastomoses

5.2.4.2 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum waveforms from:

5.2.4.2.1 Subclavian artery
5.2.4.2.2 Axillary artery
5.2.4.2.3 Brachial artery
5.2.4.2.4 Radial and ulnar arteries
5.2.4.2.5 Innominate artery when appropriate
5.2.4.2.6 Bypass graft when present, including proximal and distal anastomoses, inflow and outflow arteries

5.2.4.3 Abnormalities require additional images, waveforms and velocity measurements.

5.3 Non-imaging (physiologic) examinations if performed must include bilateral sampling from three or more levels.

5.3.1 Doppler waveforms must be documented from, but not limited to:

5.3.1.1 Common femoral artery
5.3.1.2 Popliteal artery
5.3.1.3 Distal tibial arteries at the level of the ankle

5.3.2 Plethysmographic waveforms must be documented from:

5.3.2.1 Thigh
5.3.2.2 Calf
5.3.2.3 Ankle
5.3.2.4  Toe waveforms if indicated
5.3.2.5  Toe systolic pressures if indicated

5.4  Supplemental testing, if performed may include:

Comment: Supplemental testing techniques are inadequate for use alone to diagnose and grade the severity of peripheral arterial disease.

5.4.1  Transcutaneous oximetry if performed must be documented as required by the protocol and must include at a minimum:

5.4.1.1  Measurement at a reference or baseline site.
5.4.1.2  Oxygen values at identified sites.

5.4.2  Photoplethysmography if performed must be documented as required by the protocol and must include at a minimum:

5.4.2.1  Documentation of the digital waveforms.

5.4.3  Laser Doppler if performed must be documented as required by the protocol and must include at a minimum:

5.4.3.1  Documentation of all flow data.

5.4.4  Treadmill exercise/stress testing if performed must be documented as required by the protocol and must include at a minimum:

5.4.4.1  Pressures obtained at rest.
5.4.4.2  Pressures obtained at timed intervals immediately after exercise.
5.4.4.3  For treadmill-based protocols, the time of onset of claudication and maximal walking time must be recorded.

5.4.5  Abdominal aorta examinations if performed must be documented as required by the protocol.

Comment: The laboratory can include abdominal aorta examinations as part of the peripheral arterial application only if the laboratory performs other peripheral arterial examinations. If the laboratory does not perform any other peripheral arterial examinations, abdominal aorta examinations can be included in the visceral vascular testing section.

5.4.5.1  Transverse view gray scale images with diameter measurements perpendicular to the long axis of the aorta must be documented as required by the protocol and must include at a minimum:

5.4.5.1.1  Proximal aorta
5.4.5.1.2  Mid aorta
5.4.5.1.3  Distal aorta
5.4.5.1.4  Common iliac arteries at the bifurcation
5.4.5.2 Longitudinal view gray scale images must be documented as required by the protocol and must include at a minimum:

5.4.5.2.1 Proximal aorta
5.4.5.2.2 Mid aorta
5.4.5.2.3 Distal aorta
5.4.5.2.4 Documentation of aneurysms, if present, must include the widest size of the aorta measured outer wall to outer wall.
5.4.5.2.5 Additional images proximal and distal to the aneurysm must be recorded.

5.4.5.3 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

5.4.5.3.1 Aorta at/or proximal to the renal artery origins
5.4.5.3.2 Mid aorta
5.4.5.3.3 Distal aorta
5.4.5.3.4 Right common iliac artery
5.4.5.3.5 Left common iliac artery

Comment: Color Doppler images may supplement gray scale imaging but does not substitute for it.

STANDARD – Diagnostic Criteria

6.1 Each examination performed in the laboratory must have a single set of written, validated diagnostic criteria to interpret the presence of disease and to document its location, extent, severity and whenever possible etiology. Diagnostic criteria must be laboratory specific.

Comment: These criteria can be based on published reports or internally generated and internally validated as outlined in STANDARD – Quality Assurance.

6.1.1 For imaging equipment if used, for each examination performed there must be diagnostic criteria for the interpretation of:

6.1.1.1 Gray scale images
6.1.1.2 Spectral Doppler waveforms
6.1.1.3 Spectral Doppler velocities
6.1.1.4 Color Doppler images (if used)
6.1.1.5 Other imaging modes (if used)

6.1.2 For non-imaging equipment, there must be diagnostic criteria for interpretation of each examination performed including:

6.1.2.1 Ankle brachial index (If ABI is not performed at the time of the duplex examination, the date and results of the previous ABI must be included in the final report).
6.1.2.2 Segmental limb pressures (if used)
6.1.2.3 Continuous wave and pulsed wave Doppler waveforms (if used)

6.1.2.4 Air plethysmographic waveforms (if used)

6.1.2.5 Supplemental testing, if used, must have diagnostic criteria for interpretation of:

6.1.2.5.1 Transcutaneous tissue oxygen pressures
6.1.2.5.2 Photoplethysmography signal amplitude and waveform
6.1.2.5.3 Laser Doppler
6.1.2.5.4 Treadmill exercise/stress testing
6.1.2.5.5 Abdominal aorta examination for aneurysm and/or stenosis

**STANDARD – Interpretation**

7.1 Interpretation using the documented findings and the diagnostic criteria must be performed by the Medical Director or a member of the medical staff to indicate the absence or presence of abnormalities in the sites and vessels that were examined.

7.1.1 Disease, if present, must be characterized according to:

7.1.1.1 Location
7.1.1.2 Extent
7.1.1.3 Severity
7.1.1.4 Etiology whenever possible

Comment: For the requirements of interpretation/final report, refer to SECTION 4 – Examination Interpretation, Reports and Records in Part I: Organization.

**STANDARD – Quality Assurance**

8.1 Quality assurance must be performed.

8.1.1 There must be a written policy regarding quality assurance for all procedures performed in the laboratory.

8.1.2 Results of peripheral arterial examinations must be regularly correlated with other imaging modalities, preferably angiographic and/or surgical findings as described below.

8.1.2.1 The laboratory must have a written procedure for regular correlation of the peripheral arterial examinations with angiographic findings produced by digital subtraction angiography, contrast enhanced computed tomography, magnetic resonance angiography or operative findings.

8.1.2.2 The correlation must be reported using the comparison of the results of the peripheral arterial examination and the results of the validating study with regard to the location and severity of the disease as defined by the diagnostic criteria utilized by the laboratory.

8.1.2.3 A minimum of 30 extremities must be correlated.
Comment: The time interval between the vascular laboratory examination and the correlative study for quality assurance purposes should be appropriate for the disease being correlated. For diseases which may change rapidly (e.g., vasospasm), a short time interval is appropriate. For diseases which generally change more slowly (e.g., atherosclerosis) and where there has been no change in signs or symptoms, a longer interval is acceptable. Many current clinical trials of atherosclerotic disease accept a 90-120 day interval between an imaging study and enrollment. Confirmation of a normal vessel also may have a longer interval before correlation is performed. If the patient’s signs or symptoms change in the interval between the vascular laboratory examination and the correlative study, comparison of these studies is not an acceptable quality assurance mechanism.

8.1.2.4 The correlation log must demonstrate greater than 70% accuracy agreement.

8.1.2.5 Documentation of correlation must be maintained.

Comment: The correlations submitted must have been completed within the three years preceding submission of the application. If the laboratory is unable to obtain the minimum number of correlations, alternative methods for QA may be considered on an individual laboratory basis. The laboratory must submit to the ICAVL the written plan of action for documentation of ongoing quality measures to assess the accuracy of examinations.

8.1.3 Quality assurance meetings

8.1.3.1 A minimum of two vascular laboratory quality assurance meetings per year must be held to:

8.1.3.1.1 Review the results of comparative studies
8.1.3.1.2 Address discrepancies
8.1.3.1.3 Discuss difficult cases
8.1.3.1.4 Address laboratory quality assurance issues

8.1.3.2 Minutes of the quality assurance meetings must be maintained.

STANDARD – Procedure Volumes

9.1 The annual procedure volume must be sufficient to maintain proficiency in examination techniques and interpretation.

Comment: In general, a laboratory should perform a minimum of 100 complete examinations annually.

9.1.1 Records must be maintained that permit evaluation of annual procedure volumes. These records must include:

9.1.1.1 The indication for the examination
9.1.1.2 The technologist performing the examination
9.1.1.3 The examination(s) performed
9.1.1.4 The examination findings
9.1.1.5 The physician interpreting the examination
PART V:
Vascular Laboratory Testing – Peripheral Venous

STANDARD – Indications

1.1 Peripheral venous testing must be performed for appropriate clinical indications. Venous testing comprises several distinct examinations. The components of a venous examination vary depending upon the indication(s) for testing (e.g., evaluation for deep vein thrombosis (DVT) or obstruction, reflux, assessment of calf muscle pump, vein mapping, stents, arteriovenous (AV) fistula, dialysis access grafts and others).

1.1.1 The indication for testing must be documented prior to performing the examination.

1.1.2 When available, appropriateness criteria published by medical professional organizations should be utilized.

Comment: An accepted indication is generally written by the referring health care provider. In some instances it can only be assessed at the time of the examination.

STANDARD – Equipment

2.1 Equipment must provide accurate data.

2.1.1 Imaging equipment – duplex ultrasound with color flow Doppler must be provided with:

2.1.1.1 Imaging frequencies appropriate for the structures evaluated.

2.1.1.2 Doppler frequencies appropriate for the vessels evaluated.

2.1.1.3 Range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest.

2.1.1.4 A Doppler angle which is measurable and adjustable.

2.1.1.5 A visual display and a permanent recording of the image.

2.1.1.6 A visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.

2.1.2 Supplemental equipment – Venous Plethysmography

Comment: This equipment is inadequate to use alone to diagnose deep vein thrombosis (DVT) or obstruction.

2.1.2.1 Devices may include impedance plethysmography, strain gauge plethysmography, photoplethysmography and air plethysmography.
All strain gauges, pneumatic cuffs, electrodes, tourniquets, and/or other sensors or devices must be appropriate for the veins and structures evaluated.

The instrument must be capable of providing a permanent recording.

Equipment quality control

Equipment used for diagnostic testing must be maintained in good operating condition.

Equipment maintenance must include, but is not necessarily limited to:

- Recording of the method and frequency of maintenance of all imaging equipment and non-imaging equipment.
- Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.
- Establishment of and adherence to an equipment cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to specifications of the manufacturer.

Comment: The cleaning schedule for each system will depend on the degree of use and should be frequent enough to allow for accurate collection of data.

STANDARD – Protocols

Each examination performed in the laboratory must have a written protocol. The protocol must include:

- The equipment to be used for each examination.
- The elements of proper technique (also see STANDARD – Techniques).
- The anatomic extent that constitutes a complete examination. A complete examination includes evaluation of the entire course of the accessible portions of each vein.

The laboratory must have a written protocol to determine the anatomic extent of the study and when a unilateral or bilateral study is to be performed.

When testing is tailored to specific indications, a protocol for each type of examination must be written.

Any variations in technique and documentation for examinations performed for the assessment of peripheral vascular interventions, including but not limited to sites of stenting and/or dialysis access, must be described.

Variations in technique and documentation for recurring limited examinations must be described.

Comment: A complete examination includes evaluation of the entire course of the accessible portions of each vein. A limited examination is a subset of the complete examination. There may be recurring indications for a limited examination.
The protocol should include the indications for a limited examination and the descriptions of the limited examination. Separate limited examination protocols may also be written.

3.1.4 The documentation that must be acquired for normal examinations and the additional documentation that must be acquired to describe abnormalities, if present (also see STANDARD – Documentation).

3.1.5 A description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement gray scale imaging and spectral Doppler measurements.

3.1.6 If plethysmography is utilized, the techniques and maneuvers used to assess obstruction, reflux, calf muscle pump function, and/or any other specific venous pathology that may be evaluated.

3.1.7 If vein mapping is performed, the techniques and maneuvers performed and the measurements obtained.

STANDARD – Techniques

4.1 Appropriate techniques must be used for the evaluation of veins, stents, arteriovenous (AV) fistula and dialysis access grafts to assess for the presence of any abnormalities and to document their severity, location, extent and whenever possible etiology.

4.1.1 Elements of proper technique include, but are not limited to:

4.1.1.1 Performance of an examination according to the written, laboratory specific protocol.

4.1.1.2 Proper patient positioning.

4.1.1.3 Patient preparation, if appropriate.

4.1.1.4 Appropriate equipment selection and placement.

4.1.1.5 Optimization of equipment gain and display settings.

4.1.1.6 Appropriate transducer selection.

4.1.1.7 Proper sample volume size and positioning.

4.1.2 For imaging equipment, elements of proper technique include, but are not limited to:

4.1.2.1 Proper measurements as required by the protocol.

4.1.2.2 Identification of veins by imaging and Doppler.

4.1.3 Duplex ultrasonography for the venous examination must include:

4.1.3.1 Transverse gray scale imaging without and with transducer compressions.

4.1.3.2 Long axis spectral Doppler evaluation with or without color imaging.

4.1.3.3 The entire length of the veins must be evaluated for assessing venous patency.
4.1.3.4 Evaluation with the lower extremities dependent, using proper maneuvers and measurement of duration of retrograde flow, if present, for assessing reflux.

4.1.3.4.1 The protocol must specify the patient position(s) to be used (e.g., standing, sitting, reverse Trendelenburg at least 15 degrees) to maintain lower extremity dependency for assessing reflux.

4.1.3.5 Assessment of patency and size of the veins of interest for the performance of vein mapping.

4.1.3.6 Gray scale images, color Doppler and velocity measurements when assessing stents, arteriovenous (AV) fistula and dialysis access grafts.

4.1.4 Venous plethysmography/venous physiologic testing must include:

4.1.4.1 Venous refilling time measured and recorded in response to passive emptying or calf muscle exercise when assessing reflux.

4.1.4.1.1 If the venous refilling time is abnormal, the study may be repeated using tourniquets.

4.1.4.2 Occluding cuffs and/or tourniquets as well as any sensing devices placed and fastened appropriately on the extremity.

4.1.4.3 Sensors properly connected to the instrument used.

STANDARD – Documentation

5.1 Each peripheral venous examination performed in the laboratory must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:

5.1.1 Gray scale images

5.1.2 Color Doppler images

5.1.3 Doppler waveforms

5.1.4 Velocity measurements as required by the protocol

5.1.5 Other images and waveforms as required by the protocol

5.1.6 Other measurements as required by the protocol

5.2 For imaging equipment, abnormalities require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology.

5.2.1 Documentation of areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.

5.2.2 Documentation of sites of peripheral vascular intervention, including but not limited to sites of stenting, must include representative Doppler waveforms and velocity measurements recorded from the proximal, mid and distal site.
5.2.3 Lower extremity venous duplex for thrombosis and patency

5.2.3.1 Transverse gray scale images without and with transducer compressions (when anatomically possible or not contraindicated) for assessing venous patency of the lower extremity must be documented as required by the protocol and must include at a minimum:

5.2.3.1.1 Common femoral vein
5.2.3.1.2 Saphenofemoral junction
5.2.3.1.3 Proximal femoral vein
5.2.3.1.4 Mid femoral vein
5.2.3.1.5 Distal femoral vein
5.2.3.1.6 Popliteal vein
5.2.3.1.7 Posterior tibial veins
5.2.3.1.8 Peroneal veins
5.2.3.1.9 Additional images to document areas of suspected thrombus.
5.2.3.1.10 Additional images if required by the laboratory protocol.

Comment: Additional sites may be required by the laboratory protocol or when indicated – common iliac, external iliac, great saphenous, small saphenous, proximal deep femoral, gastrocnemius, soleal, anterior tibial or perforating veins or inferior vena cava.

Comment: When indicated or required by the laboratory’s written protocol, vein size measurements must be recorded.

5.2.3.2 Spectral Doppler waveforms for assessing venous patency of the lower extremity showing variations with respiration and/or flow augmentation must be documented as required by the protocol and must include at a minimum:

5.2.3.2.1 Right and left common femoral veins.
5.2.3.2.2 Popliteal vein
5.2.3.2.3 Additional waveforms if required by the laboratory protocol.

Comment: For unilateral examinations, spectral Doppler waveforms must be documented from the right and left common femoral veins.

Comment: Additional sites may be required by the laboratory protocol or when indicated – iliac, external iliac, femoral, proximal deep femoral, deep calf, great saphenous or small saphenous veins or inferior vena cava.

5.2.4 Lower extremity venous duplex for reflux

5.2.4.1 Transverse gray scale images for assessing venous reflux 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:

5.2.4.1.1 Common femoral vein
5.2.4.1.2 Saphenofemoral junction
5.2.4.1.3 Mid femoral vein
5.2.4.1.4 Great saphenous vein
5.2.4.1.5 Popliteal vein
5.2.4.1.6 Small saphenous vein
5.2.4.1.7 Additional images to document areas of suspected thrombus.
5.2.4.1.8 Additional images if required by the laboratory protocol.
Comment: Additional sites may be required by the laboratory protocol or when indicated – common iliac, external iliac, proximal deep femoral, deep calf, or perforating veins or inferior vena cava.

5.2.4.2 Spectral Doppler waveforms for assessing venous reflux showing baseline and response to physiologic maneuvers must be documented as required by the protocol and include at a minimum:

5.2.4.2.1 Common femoral vein
5.2.4.2.2 Saphenofemoral junction
5.2.4.2.3 Great saphenous vein
5.2.4.2.4 Femoral vein
5.2.4.2.5 Popliteal vein
5.2.4.2.6 Small saphenous vein
5.2.4.2.7 Suspected areas of reflux including representative spectral Doppler waveforms.
5.2.4.2.8 Additional waveforms if required by the laboratory protocol.

Comment: Additional sites may be required by the laboratory protocol or when indicated – common iliac, external iliac, proximal deep femoral, deep calf, perforating veins or other accessory venous tributaries, inferior vena cava.

5.2.4.3 Representative color Doppler images must be documented as required by the protocol.

5.2.5 Upper extremity venous duplex for thrombosis and patency

5.2.5.1 Transverse gray scale images without and with transducer compressions (when anatomically possible or not contraindicated) for assessing venous patency of the upper extremity must be documented and include:

5.2.5.1.1 Internal jugular vein
5.2.5.1.2 Subclavian vein
5.2.5.1.3 Axillary vein
5.2.5.1.4 Brachial vein(s)
5.2.5.1.5 Basilic vein
5.2.5.1.6 Cephalic vein
5.2.5.1.7 Additional images to document areas of suspected thrombus.
5.2.5.1.8 Additional images if required by the laboratory protocol

Comment: Additional sites may be required by the laboratory protocol or when indicated – Jugular/subclavian vein junction, brachiocephalic (innominate) vein or forearm veins.

Comment: When indicated or required by the laboratory’s written protocol, vein size measurements must be recorded.

5.2.5.2 Spectral Doppler waveforms for assessing venous patency of the upper extremity showing variations with respiration and flow augmentation must be documented as required by the protocol and must include at a minimum:

5.2.5.2.1 Internal jugular vein
5.2.5.2.2 Right and left subclavian veins
5.2.5.2.3 Axillary vein
5.2.5.2.4 Additional waveforms if required by the laboratory protocol
Comment: For unilateral examinations, spectral Doppler waveforms must be documented from the right and left subclavian vein.

Comment: Additional sites may be required by the laboratory protocol or when indicated – Jugular/subclavian confluence, brachiocephalic (innominate) vein, brachial vein, basilic vein, cephalic vein or forearm veins

5.2.5.3 Representative color Doppler images must be documented as required by the protocol.

5.2.6 Plethysmography, if performed, must include documentation of:

5.2.6.1 Baseline data recordings

5.2.6.2 Response to appropriate physiologic maneuvers

5.2.7 Vein mapping, if performed, must include:

5.2.7.1 Assessment of the veins required by the laboratory protocol

5.2.7.2 Vein patency and size

5.2.8 Venous stents, if present, must include documentation of:

5.2.8.1 Representative waveforms and velocity measurements recorded from the proximal, mid and distal stent.

5.2.9 Arteriovenous (AV) fistula or dialysis access grafts, if present, must include documentation of:

5.2.9.1 Gray scale images

5.2.9.2 Color Doppler

5.2.9.3 Velocity measurements at the proximal and distal anastomoses, inflow and outflow vessels

STANDARD – Diagnostic Criteria

6.1 Each peripheral venous examination performed in the laboratory must have a single set of written, validated diagnostic criteria to interpret the presence of disease and to document its location, extent, severity, and whenever possible etiology.

6.1.1 Diagnostic criteria must be laboratory specific.

Comment: These criteria can be based on published reports or internally generated and internally validated as outlined in STANDARD – Quality Assurance.

6.1.2 For imaging equipment, for each examination performed there must be diagnostic criteria for the interpretation of:

6.1.2.1 Gray scale images

6.1.2.2 Spectral Doppler waveforms
6.1.2.3 Spectral Doppler velocities (if used)
6.1.2.4 Color Doppler images (if used)
6.1.2.5 Other imaging modes (if used)

6.1.3 For non-imaging instrumentation, there must be criteria for interpretation for each examination performed and for each technique which may include plethysmographic waveforms and/or other measurements.

6.1.4 There must be diagnostic criteria for interpretation of:
6.1.4.1 Thrombosis and thrombus aging
6.1.4.2 Patency
6.1.4.3 Vein size
6.1.4.4 Valve competence if assessing reflux
6.1.4.5 Arteriovenous (AV) fistula or dialysis access grafts

STANDARD – Interpretation

7.1 Interpretation using the documented findings and the diagnostic criteria must be performed by the Medical Director or a member of the medical staff to indicate the absence or presence of abnormalities in the sites and vessels that were examined.

7.1.1 Disease, if present, must be characterized according to:
7.1.1.1 Location
7.1.1.2 Extent
7.1.1.3 Severity
7.1.1.4 Etiology whenever possible

Comment: For the requirements of interpretation/final report, refer to SECTION 4 – Examination Interpretation, Reports and Records in Part I: Organization.
STANDARD – Quality Assurance

8.1 Quality assurance must be performed.

8.1.1 There must be a written policy regarding quality assurance for all peripheral venous procedures performed in the lab.

8.1.2 Results of peripheral venous examinations must be regularly correlated with other imaging modalities and/or surgical findings as described below.

8.1.2.1 Acceptable methods for correlation include, but are not limited to:

8.1.2.1.1 Repeat examination by a second examiner at the same setting
8.1.2.1.2 Clinical outcome
8.1.2.1.3 Over-reading of the final interpretation
8.1.2.1.4 Comparison with venography or surgical pathology

8.1.2.2 The correlation must be reported using the comparison of the results of the peripheral venous examination and the results of the validating study with regard to the location and severity of the disease as defined by the diagnostic criteria utilized by the laboratory.

8.1.2.3 A minimum of 30 extremities must be correlated.

Comment: The time interval between the vascular laboratory examination and the correlative study for quality assurance purposes should be appropriate for the disease being correlated. For diseases which may change rapidly (e.g., vasospasm), a short time interval is appropriate. For diseases which generally change more slowly (e.g., atherosclerosis) and where there has been no change in signs or symptoms, a longer interval is acceptable. Many current clinical trials of atherosclerotic disease accept a 90-120 day interval between an imaging study and enrollment. Confirmation of a normal vessel also may have a longer interval before correlation is performed. If the patient’s signs or symptoms change in the interval between the vascular laboratory examination and the correlative study, comparison of these studies is not an acceptable quality assurance mechanism.

8.1.2.4 The correlation log must demonstrate greater than 70% accuracy agreement.

8.1.2.5 Documentation of correlation must be maintained.

Comment: The correlations submitted must have been completed within the three years preceding submission of the application. If the laboratory is unable to obtain the minimum number of correlations, alternative methods for QA may be considered on an individual laboratory basis. The laboratory must submit the written plan of action for documentation of ongoing quality measures to assess the accuracy of examinations.

8.1.3 Quality assurance meetings

8.1.3.1 A minimum of two vascular laboratory quality assurance meetings per year must be held to:

8.1.3.1.1 Review the results of comparative studies
8.1.3.1.2 Address discrepancies
8.1.3.1.3 Discuss difficult cases
8.1.3.1.4 Address laboratory quality assurance issues

8.1.3.2 Minutes of the quality assurance meetings must be maintained.
**STANDARD – Procedure Volumes**

9.1 The annual procedure volume must be sufficient to maintain proficiency in examination techniques and interpretation.

Comment: In general, a laboratory should perform a minimum of 100 complete examinations annually.

9.1.1 Records must be maintained that permit evaluation of annual procedure volumes. These records must include:

- 9.1.1.1 The indication for the examination
- 9.1.1.2 The technologist performing the examination
- 9.1.1.3 The examination(s) performed
- 9.1.1.4 The examination findings
- 9.1.1.5 The physician interpreting the examination
PART VI:  
Vascular Laboratory Testing –  
Visceral Vascular

STANDARD – Indications

1.1 Visceral vascular testing must be performed for appropriate clinical indications.

1.1.1 The indication for testing must be documented prior to performing the examination.

1.1.2 When available, appropriateness criteria published by medical professional organizations should be utilized.

Comment: An accepted indication is generally written by the referring health-care provider. In some instances it can only be assessed at the time of the examination.

STANDARD – Equipment

2.1 Equipment must provide accurate data.

2.1.1 Imaging equipment – Duplex ultrasound with color flow Doppler must be provided with:

2.1.1.1 Imaging frequencies appropriate for the structures evaluated.

2.1.1.2 Doppler frequencies appropriate for the vessels evaluated.

2.1.1.3 Range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest.

2.1.1.4 A Doppler angle which is measurable and adjustable.

2.1.1.5 A visual display and a permanent recording of the image.

2.1.1.6 A visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.

2.1.2 Equipment quality control

2.1.2.1 Equipment used for diagnostic testing must be maintained in good operating condition.

2.1.2.2 Equipment maintenance must include, but is not necessarily limited to:

2.1.2.2.1 Recording of the method and frequency of maintenance of all imaging equipment and non-imaging equipment.

2.1.2.2.2 Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.
2.1.2.2.3 Establishment of and adherence to an equipment cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to specifications of the manufacturer.

Comment: The cleaning schedule for each system will depend on the degree of use and should be frequent enough to allow for accurate collection of data.

STANDARD – Protocols

3.1 Each examination performed in the laboratory must have a written protocol.

3.1.1 The protocol must include:

3.1.1.1 The equipment to be used for each examination.

3.1.1.2 The elements of proper technique (also see STANDARD – Techniques).

3.1.1.3 The anatomic extent that constitutes a complete examination.

3.1.1.3.1 Any variations in technique and documentation for examinations performed for the assessment of peripheral vascular interventions, including but not limited to sites of stenting, must be described.

3.1.1.3.2 Variations in technique and documentation for recurring limited examinations must be described.

Comment: A complete examination includes evaluation of the entire course of the accessible portions of each vessel. A limited examination is a subset of the complete examination. There may be recurring indications for a limited examination. The protocol should include the indications for a limited examination and the descriptions of the limited examination. Separate limited examination protocols may also be written.

3.1.1.4 The documentation that must be acquired for normal examinations and the additional documentation that must be acquired to describe abnormalities, if present (also see STANDARD – Documentation).

3.1.1.5 A description of how color Doppler or other flow imaging modes (e.g. power Doppler) are used to supplement gray scale imaging, spectral Doppler and velocity measurements.

3.1.2 Visceral vascular examinations comprise the following visceral vascular systems:

3.1.2.1 Mesenteric arterial system

3.1.2.2 Hepatoportal system

3.1.2.3 Renal vasculature

3.1.2.4 Renal transplant

3.1.2.5 Liver transplant
3.1.3 Visceral vascular testing comprises several distinct examinations because different indications require specific vascular systems to be evaluated.

3.1.3.1 Each visceral vascular system requires several vessels to be examined.

3.1.3.2 Some examinations also require gray scale imaging of the appropriate organ.

Comment: Laboratories may seek accreditation in one or more visceral vascular systems. Laboratories must seek accreditation for all of the visceral vascular systems they examine.

STANDARD – Techniques

4.1 Appropriate techniques must be used for the evaluation of each visceral vascular system to assess for the presence of any abnormalities and to document their severity, location, extent and whenever possible etiology.

4.1.1 Elements of proper technique include, but are not limited to:

4.1.1.1 Performance of an examination according to the written, laboratory specific protocol.

4.1.1.2 Proper patient positioning.

4.1.1.3 Patient preparation, if appropriate.

Comment: Patient preparation may be necessary in order to minimize abdominal gas. This may include fasting and/or gas reducing medication.

4.1.1.4 Appropriate equipment selection and placement.

4.1.1.5 Optimization of equipment gain and display settings.

4.1.1.6 Appropriate transducer selection.

4.1.1.7 Proper sample volume size and positioning.

4.1.2 For imaging equipment, elements of proper technique include, but are not limited to:

4.1.2.1 A spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities.

4.1.2.2 Proper measurement of spectral velocities as required by the protocol.

4.1.2.3 Identification of vessels by imaging and Doppler.
STANDARD – Documentation

5.1 Each visceral vascular examination performed in the laboratory must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:

5.1.1 Gray scale images
5.1.2 Color Doppler images
5.1.3 Doppler waveforms
5.1.4 Velocity measurements
5.1.5 Other images and waveforms as required by the protocol
5.1.6 Other measurements as required by the protocol

5.2 For imaging equipment, abnormalities require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.

5.2.1 Documentation of areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.

5.2.2 Documentation of sites of peripheral vascular intervention, including but not limited to sites of stenting, must include representative Doppler waveforms and velocity measurements recorded from the proximal, mid and distal site.

5.2.3 Mesenteric arterial system

5.2.3.1 Gray scale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

5.2.3.1.1 Adjacent aorta
5.2.3.1.2 Celiac artery
5.2.3.1.3 Superior mesenteric artery
5.2.3.1.4 Inferior mesenteric artery

5.2.3.2 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

5.2.3.2.1 Adjacent aorta
5.2.3.2.2 Celiac artery origin
5.2.3.2.3 Splenic and hepatic artery (when appropriate)
5.2.3.2.4 Superior mesenteric artery origin
5.2.3.2.5 Proximal superior mesenteric artery
5.2.3.2.6 Inferior mesenteric artery

5.2.4 Hepatoportal system

5.2.4.1 Gray scale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:
5.2.4.1 Intrathoracic vascular structures

- Intrahepatic portal vein
- Extrahepatic portal vein
- Hepatic veins
- Inferior vena cava
- Adjacent liver parenchyma
- Portosystemic shunts or collateral pathways (when present)

5.2.4.2 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- Main portal vein
- Right portal vein
- Left portal vein
- Superior mesenteric vein
- Splenic vein
- Right, left and middle hepatic veins
- Inferior vena cava
- Portosystemic shunts (when present)

5.2.4.3 Transjugular Intrahepatic Portosystemic Shunt (TIPS) require angle corrected waveforms and velocity measurements, must be documented as required by the protocol and must include at a minimum:

- Portal vein inflow
- Portal end stent
- Mid stent
- Hepatic end stent
- Hepatic vein outflow (does not require velocity measurements)

5.2.5 Renal Vasculature

5.2.5.1 Gray scale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

- Adjacent aorta at the level of the renal arteries
- Renal arteries
- Renal veins
- Gray scale pole to pole renal length measurements

5.2.5.2 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- Adjacent aorta at the level of the renal arteries
- Proximal main renal artery
- Mid main renal artery
- Distal main renal artery
- Parenchymal/hilar arteries (when appropriate)
- Accessory renal artery (when present)
- Renal veins, when appropriate (does not require velocity measurements)

Comment: A complete renal vasculature examination includes a bilateral evaluation.
5.2.6 Renal transplant

5.2.6.1 Gray scale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

- 5.2.6.1.1 Transplant renal artery
- 5.2.6.1.2 Transplant renal vein
- 5.2.6.1.3 Gray scale images of transplant kidney and peri-transplant region

5.2.6.2 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- 5.2.6.2.1 Donor artery
- 5.2.6.2.2 Arterial anastomosis
- 5.2.6.2.3 Proximal transplant renal artery
- 5.2.6.2.4 Distal transplant renal artery
- 5.2.6.2.5 Parenchymal vessels
- 5.2.6.2.6 Transplant renal vein (does not require velocity measurements)
- 5.2.6.2.7 Renal vein anastomosis (does not require velocity measurements)

5.2.7 Liver transplant

5.2.7.1 Gray scale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

- 5.2.7.1.1 Intrahepatic portal vein
- 5.2.7.1.2 Extrahepatic portal vein
- 5.2.7.1.3 Hepatic veins
- 5.2.7.1.4 Hepatic artery
- 5.2.7.1.5 Inferior vena cava
- 5.2.7.1.6 Gray scale images of transplant liver and peri-transplant region

5.2.7.2 Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- 5.2.7.2.1 Donor artery
- 5.2.7.2.2 Main hepatic artery
- 5.2.7.2.3 Hepatic veins (does not require velocity measurements)
- 5.2.7.2.4 Portal vein anastomosis (does not require velocity measurements)
- 5.2.7.2.5 Portal vein (does not require velocity measurements)
- 5.2.7.2.6 Inferior vena cava (does not require velocity measurements)

Supplemental testing

5.2.8 Abdominal aorta

Comment: The laboratory can include abdominal aorta examinations as part of the visceral vascular application only if the laboratory performs other visceral vascular examinations. If the laboratory does not perform any other visceral vascular examinations, abdominal aorta examinations can be included in the peripheral arterial testing section.

5.2.8.1 Transverse view gray scale images with diameter measurements perpendicular to the long axis of the aorta must be documented as required by the protocol and must include at a minimum:

- 5.2.8.1.1 Proximal aorta
5.2.8.1.2  Mid aorta  
5.2.8.1.3  Distal aorta  
5.2.8.1.4  Common iliac arteries at the bifurcation  

5.2.8.2  Longitudinal view gray scale images must be documented as required by the protocol and must include at a minimum:  
5.2.8.2.1  Proximal aorta  
5.2.8.2.2  Mid aorta  
5.2.8.2.3  Distal aorta  
5.2.8.2.4  Documentation of aneurysms, if present, must include the widest size of the aorta measured outer wall to outer wall.  
5.2.8.2.5  Additional images proximal and distal to the aneurysm must be recorded.  

5.2.8.3  Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:  
5.2.8.3.1  Aorta at/or proximal to the renal artery origins  
5.2.8.3.2  Mid aorta  
5.2.8.3.3  Distal aorta  
5.2.8.3.4  Right common iliac artery  
5.2.8.3.5  Left common iliac artery  

Comment: Color Doppler images may supplement gray scale imaging but does not substitute for it.  

STANDARD – Diagnostic Criteria  

6.1  Each visceral vascular examination performed in the laboratory must have a single set of written, validated diagnostic criteria to interpret the presence of disease and to document its location, extent, severity and whenever possible etiology.  

6.1.1  Diagnostic criteria must be laboratory specific.  

Comment: These criteria can be based on published reports or internally generated and internally validated as outlined in STANDARD – Quality Assurance.  

6.1.2  For imaging equipment, for each visceral vascular examination performed there must be diagnostic criteria for the interpretation of:  

6.1.2.1  Gray scale images  
6.1.2.2  Plaque morphology (if used)  
6.1.2.3  Spectral Doppler waveforms  
6.1.2.4  Spectral Doppler velocities (if used)  
6.1.2.5  Color Doppler images (if used)  
6.1.2.6  Other imaging modes (if used)  

6.1.3  There must be diagnostic criteria for interpretation of each visceral vascular examination and stenosis criteria must be vessel specific.
STANDARD – Interpretation

7.1 Interpretation using the documented findings and the diagnostic criteria must be performed by the Medical Director or a member of the medical staff to indicate the absence or presence of abnormalities in the sites and vessels that were examined.

7.1.1 Disease, if present, must be characterized according to:

7.1.1.1 Location
7.1.1.2 Extent
7.1.1.3 Severity
7.1.1.4 Etiology whenever possible

Comment: For the requirements of interpretation/final report, refer to SECTION 4 – Examination Interpretation, Reports and Records in Part I: Organization.

STANDARD – Quality Assurance

8.1 Quality assurance must be performed.

8.1.1 There must be a written policy regarding quality assurance for all procedures performed in the laboratory.

8.1.2 Results of visceral vascular examinations must be regularly correlated with other imaging modalities, preferably angiographic and/or surgical findings as described below.

8.1.2.1 The laboratory must have a written procedure for regular correlation of the visceral vascular examinations with angiographic findings produced by digital subtraction angiography, contrast enhanced computed tomography, magnetic resonance angiography or operative findings.

8.1.2.2 The correlation must be reported using the comparison of the results of the visceral vascular examination and the results of the validating study with regard to the location and severity of the disease as defined by the diagnostic criteria utilized by the laboratory.

8.1.2.3 A minimum of 15 patient examinations must be correlated.

Comment: The time interval between the vascular laboratory examination and the correlative study for quality assurance purposes should be appropriate for the disease being correlated. For diseases which may change rapidly (e.g., vasospasm), a short time interval is appropriate. For diseases which generally change more slowly (e.g., atherosclerosis) and where there has been no change in signs or symptoms, a longer interval is acceptable. Many current clinical trials of atherosclerotic disease accept a 90-120 day interval between an imaging study and enrollment. Confirmation of a normal vessel also may have a longer interval before correlation is performed. If the patient’s signs or symptoms change in the interval between the vascular laboratory examination and the correlative study, comparison of these studies is not an acceptable quality assurance mechanism.
8.1.2.4 The correlation log must demonstrate greater than 70% accuracy agreement.

8.1.2.5 Documentation of correlation must be maintained.

Comment: The correlations submitted must have been completed within the three years preceding submission of the application. If the laboratory is unable to obtain the minimum number of correlations, alternative methods for QA may be considered on an individual laboratory basis. The laboratory must submit the written plan of action for documentation of ongoing quality measures to assess the accuracy of examinations.

8.1.3 Quality assurance meetings

8.1.3.1 A minimum of two vascular laboratory quality assurance meetings per year must be held to:

8.1.3.1.1 Review the results of comparative studies
8.1.3.1.2 Address discrepancies
8.1.3.1.3 Discuss difficult cases
8.1.3.1.4 Address laboratory quality assurance issues

8.1.3.2 Minutes of the quality assurance meetings must be maintained.

STANDARD – Procedure Volumes

9.1 The annual procedure volume must be sufficient to maintain proficiency in examination techniques and interpretation.

Comment: In general, a laboratory should perform a minimum of 100 complete examinations annually.

9.1.1 Records must be maintained that permit evaluation of annual procedure volumes. These records must include:

9.1.1.1 The indication for the examination
9.1.1.2 The technologist performing the examination
9.1.1.3 The examination(s) performed
9.1.1.4 The examination findings
9.1.1.5 The physician interpreting the examination
PART VII:
Vascular Laboratory Testing – Screening

Introduction: Laboratories must be accredited in the testing areas for which screening will be provided.

STANDARD – Indications

1.1 Screening examinations are performed to determine the presence or absence of peripheral vascular, cerebrovascular disease or to evaluate risk for cardiovascular or cerebrovascular events in participants without specific signs or symptoms.

1.1.1 Screening guidelines for the appropriate selection of participants should be based upon contemporary scientific publications.

1.1.2 Screening cannot replace diagnostic examinations for symptomatic individuals.

STANDARD – Equipment

2.1 Equipment must provide accurate data.

2.1.1 Imaging equipment – Duplex ultrasound with color flow Doppler must be provided with:

2.1.1.1 Imaging frequencies appropriate for the structures evaluated.

2.1.1.2 Doppler frequencies appropriate for the vessels evaluated.

2.1.1.3 Range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest.

2.1.1.4 A Doppler angle which is measurable and adjustable.

2.1.1.5 A visual display and a permanent recording of the image.

2.1.1.6 A visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.

2.1.2 Continuous wave (CW) and pulsed wave (PW) Doppler, if used for testing, must be provided with:

2.1.2.1 A direction sensitive Doppler blood flow meter.

2.1.2.2 Doppler transducer frequencies appropriate for the vessels evaluated, which must be at least 3 MHz or greater.

2.1.2.3 Doppler waveform display demonstrating bidirectional flow.

2.1.2.4 An audible output and a permanent recording of the waveform.
2.1.3 Cuffs of varying widths appropriate to the limb segment to be evaluated.

2.1.4 Computerized assisted electronic calipers or semiautomatic edge detection software must be utilized for CIMT.

**STANDARD – Protocols**

3.1 Each examination performed in the laboratory must have a written protocol. The protocol must include:

3.1.1 The equipment to be used for each examination.

3.1.2 The elements of proper technique (also see STANDARD – Techniques).

3.1.3 The anatomic extent that constitutes a screening examination.

3.1.3.1 Bilateral testing is considered an integral part of a screening examination.

3.1.4 The documentation that must be acquired for screening examinations and the additional documentation that must be acquired to describe abnormalities, if present (also see STANDARD – Documentation).

3.1.5 A description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement gray scale imaging, spectral Doppler and velocity measurements.

**STANDARD – Techniques**

4.1 Appropriate techniques must be used for screening examinations to assess for the presence of any abnormalities.

4.1.1 Elements of proper technique include, but are not limited to:

4.1.1.1 Performance of an examination according to the written, laboratory specific protocol.

4.1.1.2 Proper patient positioning.

4.1.1.3 Appropriate equipment selection and placement.

4.1.1.4 Optimization of equipment gain and display settings.

4.1.1.5 Appropriate transducer selection.

4.1.1.6 Proper sample volume size and positioning.

4.1.2 For imaging equipment, elements of proper technique include, but are not limited to:

4.1.2.1 A spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities.
4.1.2.2  Proper measurement of spectral velocities as required by the protocol.

4.1.2.3  Identification of vessels by imaging and Doppler.

4.1.3  The use of computerized assisted electronic calipers or semiautomatic edge detection software for CIMT measurements.

4.1.4  Peripheral arterial examinations must include performance of an ankle brachial index (ABI).

4.1.4.1  Measurement of upper extremity (brachial artery) systolic pressures must be obtained from both arms and the higher of the two pressures used to calculate the ABI.

4.1.4.2  Measurement of ankle systolic pressures must be obtained bilaterally from the distal posterior tibial (PT) artery and distal anterior tibial (AT)/dorsalis pedis (DP) artery and the higher of the two pressures on each side used to calculate the ABI.

STANDARD – Documentation

5.1  All examinations must include standard components as required by the protocol and provide sufficient documentation to allow proper interpretation including but not limited to:

5.1.1  Gray scale images

5.1.2  Doppler waveforms

5.1.3  Velocity measurements

5.1.4  Other measurements or images as required by the screening protocol

5.1.5  Extracranial cerebrovascular screening

5.1.5.1  Required techniques must include bilateral permanent recordings of spectral Doppler waveforms.

5.1.5.1.1  Normal Examination: One site in the proximal internal carotid artery with peak systolic and end diastolic velocity measurements.

5.1.5.1.2  Abnormal Examination: Peak systolic and end diastolic velocity measurements documenting area(s) of significant findings in accordance with the screening diagnostic criteria.

5.1.6  Carotid Intima-Media Thickness (CIMT) Screening (see appendix)

Comment: CIMT has been effectively used as a marker of atherosclerosis in many patient populations, and has also been used as a primary endpoint demonstrating therapeutic efficacy with different pharmacologic therapies. Studies using CIMT to make treatment decisions based on a single IMT measurement, with documentation of the outcome for specific interventions, for individual patients, are lacking. The ICAVL does not advocate use of carotid IMT as a screening method for atherosclerotic risk until further peer-reviewed literature is available. If providers choose to perform CIMT testing, rigorous methodological protocols should be strictly followed.
5.1.6.1 **Required techniques** must include but are not limited to:

5.1.6.1.1 Bilateral measurements obtained during end diastole
5.1.6.1.2 Measurements from at least three longitudinal imaging planes (optimal and two complementary imaging planes – anterior, lateral or posterior to the optimal angle).
5.1.6.1.3 Measurements obtained from the far wall of the distal 1-2 cm of the CCA. Measurements may also be obtained from the near wall of the CCA segment, as well as the near and far wall of the bifurcation and the proximal 1 cm of the ICA.
5.1.6.1.4 When plaque is present, plaque characterization and/or dimensions should be documented separately.

Read the ASE CONSENSUS STATEMENT: Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force - Endorsed by the Society for Vascular Medicine. [Download the PDF](#)

5.1.7 Peripheral arterial screening

5.1.7.1 Ankle brachial index (ABI)

5.1.7.1.1 Bilateral brachial artery systolic pressures
5.1.7.1.2 Bilateral ankle systolic pressures

5.1.8 Abdominal aorta aneurysm screening

5.1.8.1 Gray scale images must be permanently recorded of the abdominal aorta.

5.1.8.1.1 Normal Examination: One transverse image at the level of maximum width perpendicular to the long axis of the aorta with documentation of the outer wall to outer wall diameter measurement.
5.1.8.1.2 Abnormal Examination: Transverse view(s) with diameter measurements of the aorta segment(s) documenting the maximum outer wall to outer wall diameter.
5.1.8.1.3 One transverse view documenting the outer wall to outer wall diameter measurements of a non-dilated abdominal aorta segment for comparison.

**STANDARD – Diagnostic Criteria**

6.1 **Each screening examination performed in the laboratory must have a single set of written, validated diagnostic criteria to interpret the presence of disease.**

6.1.1 Diagnostic criteria must be laboratory specific.

Comment: These criteria can be based on published reports or internally generated and internally validated as outlined in **STANDARD – Quality Assurance.**

6.1.2 For imaging equipment, for each examination performed there must be diagnostic criteria for the interpretation of:

6.1.2.1 Gray scale images
6.1.2.2 Spectral Doppler waveforms
6.1.2.3 Spectral Doppler velocities
6.1.2.4 Color Doppler images (if used)

6.1.3 For non-imaging equipment, there must be diagnostic criteria for the interpretation of each examination performed.

6.1.4 Each screening examination must have examination specific diagnostic criteria.

6.1.4.1 Extracranial cerebrovascular screening
  6.1.4.1.1 Absence of disease; normal
  6.1.4.1.2 Presence of disease with no overall significance; in adherence to the laboratory specific diagnostic criteria
  6.1.4.1.3 Presence of disease with overall significance; in adherence to the laboratory specific diagnostic criteria
  6.1.4.1.4 Occlusion

6.1.4.2 Carotid intima-media thickness screening: CIMT
  6.1.4.2.1 Age, gender and race associated risk according to a standardized table of CIMT measurements should be used to generate a cardiovascular risk assessment report.
  6.1.4.2.2 The report should include standard deviations or prediction ranges for the measurements based on age and gender. Specific measurement values (i.e., mean, maximum, mean maximum) used for the risk prediction report should be the same as those used in the study(s) providing the basis for the risk prediction reporting.
  6.1.4.2.3 Plaque characteristics and dimensions should be reported separately.

6.1.4.3 Peripheral arterial screening
  6.1.4.3.1 Absence of disease; in adherence to the laboratory specific diagnostic criteria
  6.1.4.3.2 Presence of disease; in adherence to the laboratory specific diagnostic criteria
  6.1.4.3.3 Non-diagnostic ABI

6.1.4.4 Abdominal aorta aneurysm screening
  6.1.4.4.1 Absence of aneurysmal disease; in adherence to the laboratory specific diagnostic criteria
  6.1.4.4.2 Presence of aneurysmal disease; in adherence to the laboratory specific diagnostic criteria
  6.1.4.4.3 Aneurysmal status not defined due to non-visualization
STANDARD – Interpretation

7.1 Interpretation using the documented findings and the diagnostic criteria must be performed by the Medical Director or a member of the medical staff to indicate the absence or presence of abnormalities in the sites and vessels that were examined.

7.1.1 A report or documentation that describes the results of the screening examination findings and recommended follow up must be provided to the participant and/or the participant’s physician.

7.1.2 Educational materials describing the nature of vascular screening and the significance of normal and abnormal results must be provided to the participant.

7.1.3 Documentation of all screening results both negative and positive must be maintained in the laboratory.

STANDARD – Quality Assurance

8.1 Quality assurance must be performed.

8.1.1 There must be a written policy regarding quality assurance for all screening examinations performed in the laboratory.

8.1.2 Results of screening examinations must be regularly correlated with other imaging modalities, complete diagnostic noninvasive vascular examination, angiographic and/or surgical findings as described below.

8.1.2.1 The laboratory must have a written procedure for regular correlation of the vascular screening examinations with angiographic findings produced by digital subtraction angiography, contrast enhanced computed tomography, magnetic resonance angiography or operative findings.

8.1.2.2 The correlation must be reported using the comparison of the results of the screening examination and the results of the validating study with regard to the presence or absence of disease as defined by the diagnostic criteria utilized by the laboratory.

8.1.2.3 A minimum of 15 screening examination per each type of screening performed must be correlated.

Comment: The time interval between the vascular laboratory examination and the correlative study for quality assurance purposes should be appropriate for the disease being correlated. For diseases which may change rapidly (e.g., vasospasm), a short time interval is appropriate. For diseases which generally change more slowly (e.g., atherosclerosis) and where there has been no change in signs or symptoms, a longer interval is acceptable. Many current clinical trials of atherosclerotic disease accept a 90-120 day interval between an imaging study and enrollment. Confirmation of a normal vessel also may have a longer interval before correlation is performed. If the patient’s signs or symptoms change in the interval between the vascular laboratory examination and the correlative study, comparison of these studies is not an acceptable quality assurance mechanism.

8.1.2.4 For CIMT – acceptable methods for mandatory correlation include:
8.1.2.4.1  Repeat examination
8.1.2.4.2  Over-reading including recalculation of the IMT

8.1.2.5  The correlation log must demonstrate greater than 70% accuracy agreement.

8.1.2.6  Documentation of correlation must be maintained.

Comment: The correlations submitted must have been completed within the three years preceding submission of the application. If the laboratory is unable to obtain the minimum number of correlations, alternative methods for QA may be considered on an individual laboratory basis. The laboratory must submit the written plan of action for documentation of ongoing quality measures to assess the accuracy of examinations.

8.1.3  Quality assurance meetings

8.1.3.1  A minimum of two vascular laboratory quality assurance meetings per year must be held to:

8.1.3.1.1  Review the results of comparative studies
8.1.3.1.2  Address discrepancies
8.1.3.1.3  Discuss difficult cases
8.1.3.1.4  Address laboratory quality assurance issues
8.1.3.1.5  Minutes of the quality assurance meetings must be maintained.

STANDARD – Procedure Volumes

9.1  The annual procedure volume must be sufficient to maintain proficiency in examination techniques and interpretation.

Comment: In general, a laboratory should perform a minimum of 50 screening examinations per testing section annually.

9.1.1  Records must be maintained that permit evaluation of annual procedure volumes. These records must include information on:

9.1.1.1  The indication for the examination
9.1.1.2  Examination(s) performed
9.1.1.3  Findings
APPENDIX

Carotid Intima-Media Thickness (IMT)
ICAVL Executive Summary

A. IMT: Common Carotid Artery vs. Other Segments

Carotid IMT measurements are commonly obtained from the common carotid artery (CCA), as this vessel offers the easiest standardization due to its location, tubular shape, and parallel walls in most patients. In the Atherosclerosis Risk in Communities (ARIC) study involving carotid ultrasound examinations in 13,824 individuals, IMT measurements were obtainable from the CCA in 91.4%, from the bifurcation in 77.3%, and from the internal carotid artery (ICA) in 48.6% of participants.

In addition, use of the CCA IMT has correlated well with prevalent cardiovascular disease and/or outcome. In the Cardiovascular Health Study (CHS), the combination of CCA and ICA IMT resulted in similar relative risks for subsequent myocardial infarction or stroke than did CCA or ICA IMT alone (1.36 vs. 1.27 and 1.30, respectively, for 1 SD increase). Based on the ease of imaging and the general correlation with cardiovascular disease and clinical events, use of the CCA is generally advised to measure the IMT.

Some advocate evaluation of a broader/more widespread selection of arterial segments to provide a more stable and robust prediction of risk. Therefore IMT measurements must be obtained from the far wall of the distal 1-2 cm of the CCA, and may also be obtained from the near wall of the CCA segment, as well as the near and far wall of the bifurcation, and the proximal 1 cm of the ICA.

B. IMT: Far Wall vs. Near Wall

The IMT may be measured from the near (closest to the transducer) and/or the far wall. Although measurement reproducibility of the near and far walls has been reported to be comparable, measurement yield of the near wall is lower and accuracy may be less than that of the far wall due to technical considerations. Therefore, measurement is best obtained from the far wall of the CCA, and is commonly taken from the distal 1-2 cm of the distal CCA, proximal to the flow divider.

C. IMT: B-mode vs. M-mode Measurement

IMT has most commonly been measured from B-mode images. Alternatively, B-mode guided M-mode images of the distal CCA may be obtained. Whatever the method, because of the very small diameter of the intima-media layer, wall thicknesses should be measured using computer assistance with electronic calipers or semi-automated edge-detection algorithms.

D. IMT: Timing of Measurement

Variations in IMT and lumen diameter must be anticipated, and therefore, electrocardiographic-gating and/or determination of minimal (end-diastolic) and maximal (peak-systolic) diameters are important components of IMT measurements. With systolic expansion of lumen diameter, obligatory thinning of IMT will occur through conservation of mass (although some degree of longitudinal stretch will occur). Therefore, measurements must be obtained at the identical timing of the cardiac cycle (preferably at end-diastole) within a particular lab so as to avoid these physiologic changes.
E. Definition of Abnormal IMT

IMT increases with age and, on average, is larger in men than women. In addition, modest racial differences in IMT have been reported. Thus, a single threshold value for abnormality, e.g., 1 mm, may result in systematic under-detection of abnormality in younger individuals and over-detection in older individuals. Therefore, a standardized table of IMT measurements accounting for age, gender, and race must be used to determine the true value of single IMT measurements. The extent to which carotid intimal-medial thickening is a manifestation of early or diffuse atherosclerosis, as opposed to smooth muscle hypertrophy and/or hyperplasia induced by pressure overload and/or age-related sclerosis, remains uncertain.

Internal diameter of the vessel lumen (usually the CCA) can be measured at a single point in time from B-mode images, and determination of minimum and maximum lumen diameters is mandatory for assessment of vascular mechanics.

F. Non-Obstructive Plaque

Plaque characterization or dimensions should not be incorporated into IMT measurements, and must be reported separately in those cases where plaque is present.

Plaque is defined as:

i. Focal structure encroaching in the lumen >0.5 mm OR
ii. 50% of the surrounding intima-media thickness OR
iii. Plaque thickness >1.5 mm.

Process

Carotid IMT measurements should be performed by technologists with training and experience in vascular ultrasound testing. IMT measurements are obtained with the patient in the supine position with the neck slightly hyperextended and the head rotated to the opposite side. High frequency ultrasound probes are used, with a frequency of >7 MHz. Measurements are obtained in the distal CCA, 1-2 cm from the flow divider, in the far wall, using automated edge detection software, commonly available from ultrasound manufacturers. Measurements should be obtained from both vessels. Plaque should be reported separately from the IMT measurements. IMT measurements should ideally be reported using tables that account for age, race, and gender. Laboratories must submit internally validated diagnostic criteria based on their experience and published literature. In addition, laboratories must develop patient education tools that will assist in educating patients on the meaning of the carotid IMT and the importance of risk factor intervention to modify cardiovascular risk.

Finally, all laboratories must provide details of their internal quality assurance programs to support the performance of carotid IMT measurements.

Summary

CIMT has been effectively used as a marker of atherosclerosis in many patient populations, and has also been used as a primary endpoint demonstrating therapeutic efficacy with different pharmacologic therapies. Studies using CIMT to make treatment decisions based on a single IMT measurement, with documentation of the outcome for specific interventions, for individual patients, are lacking. The ICAVL does not advocate use of carotid IMT as a screening method for atherosclerotic risk until further peer-reviewed literature is available. If providers choose to perform CIMT testing, rigorous methodological protocols should be strictly followed.
SELECTED REFERENCES


