



VASCULAR TESTING

# **IAC Standards and Guidelines for Vascular Testing Accreditation**

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# Introduction

The Intersocietal Accreditation Commission (IAC) accredits imaging facilities specific to vascular testing. IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide.

A vascular testing facility 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 facility. All interpreting physicians (medical staff) and practicing technologists/sonographers (technical staff) must be adequately trained and experienced to interpret and perform noninvasive vascular testing respectively.

The intent of the accreditation process is two-fold. It is designed to recognize facilities that provide quality vascular testing services. It is also designed to be used as an educational tool to improve the overall quality of the facility.

The following are the specific areas of vascular testing for which accreditation may be obtained:

- extracranial cerebrovascular
- peripheral arterial
- intracranial cerebrovascular
- peripheral venous
- visceral vascular
- screening

These accreditation Standards and Guidelines are the minimum Standards for accreditation of vascular testing facilities. Standards are the minimum requirements to which an accredited facility is held accountable. *Guidelines are descriptions, examples, or recommendations that elaborate on the Standards. Guidelines are not required, but can assist with interpretation of the Standards.*

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

Standards that are highlighted are content changes that were made as part of the February 1, 2015 revision. These Standards will become effective on July 1, 2015. Facilities applying for accreditation after July 1, 2015 must comply with these new highlighted Standards.

In addition to all Standards listed below, the facility, including all staff, must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

# Part A:

## Organization

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### Section 1A: Personnel and Supervision

#### STANDARD – Medical Director

1.1A The Medical Director must be a licensed physician, MD or DO, in the state or jurisdiction of the facility and must be qualified to interpret noninvasive vascular examinations.

##### 1.1.1A Medical Director Required Training and Experience

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

1.1.1.1A Formal Training – Completion of a residency or fellowship that includes appropriate didactic and clinical vascular testing experience as an integral part of the program. For those testing areas in which training is provided, the physician must have **recent experience within the past three years** in interpreting the following minimum number of diagnostic studies under supervision:

- i. extracranial cerebrovascular – 100 cases
- ii. intracranial cerebrovascular – 100 cases
- iii. peripheral arterial physiologic – 100 cases
- iv. peripheral arterial duplex – 100 cases
- v. venous duplex ultrasound – 100 cases
- vi. visceral vascular duplex ultrasound – 75 cases

1.1.1.2A Informal Training – The informal training pathway allows for qualification of interpreting physicians through a combination of Continuing Medical Education (CME) and supervised practical and supervised interpretive experience.

- i. A minimum of 40 hours of relevant Category 1 CME credits must be acquired within the three-year period prior to the initial application.
  - 20 hours must be courses specifically designed to provide knowledge of the techniques, limitations, accuracies and methods of interpretations of noninvasive vascular examinations that the physician will interpret.
  - 20 hours may be dedicated to appropriate clinical topics relevant to noninvasive vascular testing.
  - Eight of the 40 hours must be specific to each testing area the physician will interpret.
- ii. The physician must acquire a minimum of eight hours supervised practical experience for each testing area to be interpreted; observing or participating in testing procedures in a facility accredited for vascular testing.

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

- iii. The physician must acquire experience in the interpretation of exams while under the supervision of a physician who has already met the *IAC Vascular Testing Standard*.

Experience must be acquired in each of the testing areas in which the physician will be providing interpretations for the following minimum number of studies:

- extracranial cerebrovascular – 100 cases
- intracranial cerebrovascular – 100 cases
- peripheral arterial physiologic – 100 cases
- peripheral arterial duplex – 100 cases
- venous duplex ultrasound – 100 cases
- visceral vascular duplex ultrasound – 75 cases

Comment: Interpretive experience must be documented with a letter from the supervising physician of the facility where the experience was obtained indicating the dates of participation and the number of cases in each testing area.

1.1.1.3A Established Practice – Training and experience will be considered adequate for a physician who has:

- i. met the medical staff credentialing qualifications;
- ii. has worked in a vascular facility for at least the past three years;
- iii. has interpreted at least the following number of diagnostic cases over the past three years in each of the areas that he/she will interpret:

- extracranial cerebrovascular – 300 cases
- intracranial cerebrovascular – 300 cases
- peripheral arterial physiologic – 300 cases
- peripheral arterial duplex – 300 cases
- venous duplex ultrasound – 300 cases
- visceral vascular duplex ultrasound – 225 cases

Comment: A current abnormal case study final report interpreted by each physician applying under the established practice pathway must be submitted in the application.

1.1.1.4A Physician Credential for Vascular Interpretation

- i. Registered Physician in Vascular Interpretation (RPVI)
- ii. Certification from the American Society of Neuroimaging (ASN)

Comment: ASN certification is accepted for physicians who interpret extracranial and intracranial examinations only.

#### 1.1.2A Medical Director Responsibilities

The Medical Director responsibilities include but are not limited to:

- 1.1.2.1A all clinical services provided and the quality and appropriateness of the care provided;
- 1.1.2.2A supervising the entire operation; may delegate specific duties to appropriate staff;
- 1.1.2.3A approval of the medical staff and supervision of their work;
- 1.1.2.4A 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 facility to participate in regular Quality Improvement (QI) meetings, case study review conferences, personnel interviews and other facility operations.

### 1.1.3A Continuing Medical Education (CME)

1.1.3.1A The Medical Director must show evidence for maintaining current knowledge by participating in CME courses that are relevant to noninvasive vascular testing.

Comment: To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.

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

Comment: Facility internal Quality Improvement (QI) meetings are not eligible as part of this CME requirement.

ii. 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 the RPVI credential or ASN certification;
- been employed in the facility less than one year.

*(See Guidelines on Page 13 for further recommendations.)*

## **STANDARD – Technical Director**

1.2A A qualified Technical Director must be designated for the facility. The Technical Director is generally a full-time position. If the Technical Director is not onsite full time, he/she must work a minimum of 20% of normal business hours each month. An appropriately credentialed vascular 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; and 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.

### 1.2.1A Technical Director Required Training and Experience

The Technical Director must meet the following criteria:

1.2.1.1A The Technical Director must have an appropriate credential in vascular testing:

- i. Registered Vascular Technologist (RVT);
- ii. Registered Vascular Specialist (RVS);
- iii. Registered Technologist Vascular Sonography [RT(VS)];
- iv. Registered Diagnostic Medical Sonographer in Abdomen [RDMS (AB)] (visceral vascular testing only);
- v. American Society of Neuroimaging (ASN) (extracranial and intracranial testing only);
- vi. Registered Phlebology Sonographer (RPhS) (peripheral venous testing only).

1.2.1.2A For each testing area applied for, the Technical Director must have performed the following minimum number of studies:

- i. extracranial cerebrovascular – 100 cases
- ii. intracranial cerebrovascular – 100 cases
- iii. peripheral arterial physiologic – 100 cases

- iv. peripheral arterial duplex – 100 cases
- v. venous duplex ultrasound – 100 cases
- vi. 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.

#### 1.2.2A Technical Director Responsibilities

The Technical Director responsibilities include but are not limited to:

- 1.2.2.1A must report directly to the Medical Director;
- 1.2.2.2A all facility duties as delegated by the Medical Director;
- 1.2.2.3A supervision of the technical and ancillary staff (may be delegated);
- 1.2.2.4A daily technical operation of the facility: staffing, scheduling, record keeping;
- 1.2.2.5A quality patient care;
- 1.2.2.6A technical training;
- 1.2.2.7A operation and maintenance of the equipment;
- 1.2.2.8A compliance to the *Standards* as outlined in this document.

#### 1.2.3A Continuing Medical Education (CME)

- 1.2.3.1A The Technical Director must show evidence of maintaining current knowledge by participating in CME courses that are relevant to vascular testing.

Comment: To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing examinations.

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

Comment: Facility internal Quality Improvement (QI) meetings are not eligible as part of this CME requirement.

- ii. 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 facility less than one year.

*(See Guidelines on Page 13 for further recommendations.)*

### **STANDARD – Medical Staff**

- 1.3A A qualified medical staff must be designated for the facility. All members of the medical staff must be licensed physicians, MD or DO, and must be qualified to interpret noninvasive vascular examinations.

### 1.3.1A Medical Staff Required Training and Experience

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

1.3.1.1A Formal Training – Completion of a residency or fellowship that includes appropriate didactic and clinical vascular testing facility experience as an integral part of the program. For those testing areas in which training is provided, the physician must have **recent experience within the past three years** in interpreting the following minimum number of diagnostic studies under supervision:

- i. extracranial cerebrovascular – 100 cases
- ii. intracranial cerebrovascular – 100 cases
- iii. peripheral arterial physiologic – 100 cases
- iv. peripheral arterial duplex – 100 cases
- v. venous duplex ultrasound – 100 cases
- vi. visceral vascular duplex ultrasound – 75 cases

1.3.1.2A Informal Training – The informal training pathway allows for qualification of interpreting physicians through a combination of Continuing Medical Education (CME) and supervised practical and supervised interpretive experience.

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

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

iii. The physician must acquire experience in the interpretation of examinations while under the supervision of a physician who has already met the *IAC Vascular Testing Standard*. Experience must be acquired in each of the testing areas in which the physician will be providing interpretations for the following minimum number of studies:

- extracranial cerebrovascular – 100 cases
- intracranial cerebrovascular – 100 cases
- peripheral arterial physiologic – 100 cases
- peripheral arterial duplex – 100 cases
- venous duplex ultrasound – 100 cases
- visceral vascular duplex ultrasound – 75 cases

Comment: Interpretive experience must be documented with a letter from the supervising physician of the facility where the experience was obtained indicating the dates of participation and the number of cases in each testing area.

1.3.1.3A Established Practice – Training and experience will be considered adequate for a physician who has:

- i. met the medical staff credentialing qualifications;
- ii. has worked in a vascular facility for at least the past three years;
- iii. has interpreted at least the following number of diagnostic cases over the past three years in each of the areas that he/she will interpret:

- extracranial cerebrovascular – 300 cases
- intracranial cerebrovascular – 300 cases
- peripheral arterial physiologic – 300 cases
- peripheral arterial duplex – 300 cases
- venous duplex ultrasound – 300 cases
- visceral vascular duplex ultrasound – 225 cases

Comment: A current abnormal case study final report interpreted by each physician applying under the established practice pathway must be submitted in the application.

1.3.1.4A Physician Credential for Vascular Interpretation

- i. Registered Physician in Vascular Interpretation (RPVI)
- ii. Certification from the American Society of Neuroimaging (ASN)

Comment: ASN certification is accepted for physicians who interpret extracranial and intracranial examinations only.

#### 1.3.2A Medical Staff Responsibilities

Medical staff responsibilities include but are not limited to:

- 1.3.2.1A 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.

#### 1.3.3A Continuing Medical Education (CME)

- 1.3.3.1A Each medical staff member must show evidence of maintaining current knowledge by participating in CME courses that are relevant to vascular testing.

Comment: To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.

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

Comment: Facility internal Quality Improvement (QI) meetings are not eligible as part of this CME requirement.

- ii. 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 the RPVI credential or ASN certification;
- been employed in the facility less than one year.

*(See Guidelines on Page 13 for further recommendations.)*

## STANDARD – Technical Staff

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

### 1.4.1A Technical Staff Required Training and Experience

1.4.1.1A For each testing area applied for, the technical staff member must have performed the following minimum number of studies:

- i. extracranial cerebrovascular – 100 cases
- ii. intracranial cerebrovascular – 100 cases
- iii. peripheral arterial physiologic – 100 cases
- iv. peripheral arterial duplex – 100 cases
- v. venous duplex ultrasound – 100 cases
- vi. 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.

1.4.1.2A The technical staff must have an appropriate level of training and experience by meeting one or more of the following criteria:

- i. Credential – An appropriate credential in vascular testing.

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

*(See Guidelines on Page 13 for further recommendations.)*

- ii. Formal Ultrasound Training – Successful completion of a diagnostic ultrasound or cardiovascular technology program with a concentration in vascular technology.

*(See Guidelines on Page 13 for further recommendations.)*

- iii. Post-secondary education plus 12 months full-time (at least 35 hours per week) clinical vascular testing experience plus one of the following:

- completion of a formal two-year program or equivalent in another allied health profession;
- completion of a bachelor's degree unrelated to vascular technology;
- a MD or DO degree.

- iv. Experience only:

- 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.
- These examinations must be appropriately distributed among the testing areas performed in the facility.

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

### 1.4.2A Technical Staff Responsibilities

Technical staff responsibilities include but are not limited to:

- 1.4.2.1A reporting to the Technical Director;
- 1.4.2.2A performing clinical examinations and other assigned tasks.
- 1.4.3A Continuing Medical Education (CME)
  - 1.4.3.1A The technical staff must show evidence of maintaining current knowledge by participating in CME courses that are relevant to vascular testing.  
  
Comment: To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.
  - 1.4.3.2A A minimum of 15 hours of CME is required every three years.  
  
Comment: Facility internal Quality Improvement (QI) meetings are not eligible as part of this CME requirement.
  - 1.4.3.3A The CME requirement will be waived if, in the previous three years prior to the application submission, the technical staff member has:
    - i. completed formal training;
    - ii. acquired an appropriate vascular credential;
    - iii. been employed in the facility less than one year.

*(See Guidelines on Page 13 for further recommendations)*

## **STANDARD – Trainees**

- 1.5A Training, if conducted, must not compromise patient care and must benefit the trainee.
  - 1.5.1A Trainee Requirements
    - 1.5.1.1A Supervision: The Medical Director must ensure that the responsibilities assumed by the trainee are appropriate.
    - 1.5.1.2A Trainees must perform examinations only with direct medical and/or technical staff supervision.

## **STANDARD – Support Services**

- 1.6A Ancillary personnel (clerical, nursing, transport, etc.) necessary for safe and efficient patient care must be provided.
  - 1.6.1A The Medical Director must ensure that support services are appropriate and in the best interest of patient care.
  - 1.6.2A Clerical and administrative support must be sufficient to ensure efficient facility operational record keeping.
  - 1.6.3A Nursing and ancillary services must be sufficient to ensure quality patient care.

# Section 1A: Personnel and Supervision

## Guidelines

### 1.1A Medical Director – Continuing Experience

- The monthly volume should be sufficient to maintain proficiency in exam interpretation.
- In general, the Medical Director should interpret a minimum of five noninvasive vascular examinations per month **per area of testing**.
- The total volume of interpretations may be combined from sources other than the applicant facility.

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

### 1.2A Technical Director – Continuing Experience

- The monthly volume should be sufficient to maintain proficiency in exam performance.
- In general, the Technical Director should perform a minimum of five noninvasive vascular examinations per month **per area of testing**.
- The total volume of cases may be combined from sources other than the applicant facility.

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

### 1.2.3A Technical Director – Continuing Medical Education

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

### 1.3A Medical Staff – Continuing Experience

- The monthly volume should be sufficient to maintain proficiency in examination interpretation.
- In general, the medical staff should interpret a minimum of five noninvasive vascular examinations per month **per area of testing**.
- The total volume of interpretations may be combined from sources other than the applicant facility.

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

### 1.4A Technical Staff – Continuing Experience

- The monthly volume should be sufficient to maintain proficiency in exam performance.
- In general, the technical staff should perform a minimum of five noninvasive vascular examinations per month **per area of testing**.
- The total volume of cases may be combined from sources other than the applicant facility.

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

1.4.1.2Ai Though the Standards include multiple pathways by which a technical staff member may document experience and training, the IAC encourages that all staff members acquire an appropriate credential in vascular testing.

1.4.1.2Aii 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).

## **Section 2A: Facility**

### **STANDARD – Examination Areas**

2.1A Examinations must be performed in a setting providing patient safety, comfort and privacy.

### **STANDARD – Interpretation Areas**

2.2A Adequate designated space must be provided for the interpretation of examination results and preparation of reports.

### **STANDARD – Storage**

2.3A Adequate designated space must be provided for the convenient storage of supplies, records and reports.

# Section 3A: Examination Reports and Records

## STANDARD – Records

- 3.1A Provisions must exist for the generation and retention of examination records of all studies performed.
- 3.1.1A Essential portions of all examinations must be documented on media appropriate for long-term storage.
- Comment: Final submission of representative case studies to the IAC must be in a digital format (e.g., CD, DVD or flash drive; no videotape recordings will be accepted).
- 3.1.2A A complete, accurate and signed final report must be generated as outlined in [STANDARD: Examination Interpretation and Reports](#), as part of the record of examination.
- 3.1.3A 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.

## STANDARD – Examination Interpretation and Reports

- 3.2A Noninvasive vascular examinations are interpreted and reported by the Medical Director or a member of the medical staff of the vascular testing facility.
- 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.
- 3.2.1A All reporting must be standardized.
- 3.2.2A All physicians interpreting noninvasive vascular examinations in the facility must agree on and utilize uniform diagnostic criteria and a standardized report format.
- 3.2.3A Interpretation must include review of all examination data including measurements, images and recordings by the Medical Director or a member of the medical staff.
- 3.2.4A The report must accurately reflect the content and results of the examination.
- 3.2.5A The final report must be verified and signed by the Medical Director or a member of the medical staff of the facility.
- 3.2.6A The final report must be typed and must include, but is not limited to:
- 3.2.6.1A patient identification;
  - 3.2.6.2A date of the examination;
  - 3.2.6.3A appropriate clinical indications leading to the performance of the examination;
  - 3.2.6.4A an adequate description of the examination performed and must include the name of the examination and its integral parts;

- 3.2.6.5A description of pertinent positive and negative findings, including velocity measurements;
- 3.2.6.6A if disease is present it must be characterized according to its location, extent, severity and etiology whenever possible;
- 3.2.6.7A incidental findings;
- 3.2.6.8A reasons for a technically limited, suboptimal or incomplete examination;
- 3.2.6.9A summary (impression/conclusion) of the examination findings;
- 3.2.6.10A comparison with previous related studies when available;
- 3.2.6.11A interpreting physician typed name and signature and/or electronic verification;
- 3.2.6.12A date of interpreting physician signature or verification.

*(See Guidelines on Page 20 for further recommendations.)*

- 3.2.7A The interpretation by the Medical Director or a member of the medical staff must be available within two 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 business days.

- 3.2.8A Identification of the technologist performing the examination must appear as part of the permanent record.
- 3.2.9A If preliminary findings are provided, the preliminary nature must be clearly indicated.
  - 3.2.9.1A A policy for communication of any significant changes must be defined for those situations in which the final interpretation differs substantially from the preliminary findings.
- 3.2.10A A policy 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 – Interpretation**

- 3.3A 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.
  - 3.3.1A Disease, if present, must be characterized according to:
    - 3.3.1.1A severity;
    - 3.3.1.2A location;
    - 3.3.1.3A extent;
    - 3.3.1.4A etiology whenever possible.

Comment: For the requirements of interpretation/final report, refer to [STANDARD – Examination Interpretation and Reports](#).

## STANDARD – Diagnostic Criteria

3.4A Each examination performed in the facility 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.

3.4.1A Diagnostic criteria must be based on published reports or internally generated and internally validated as outlined in [Part C: Quality Improvement](#).

### 3.5A Extracranial Cerebrovascular

3.5.1A For each extracranial cerebrovascular examination performed there must be diagnostic criteria for the interpretation of:

3.5.1.1A grayscale images;

i. plaque morphology, when reported.

3.5.1.2A spectral Doppler waveforms;

3.5.1.3A spectral Doppler velocities;

3.5.1.4A color Doppler images.

3.5.2A There must be diagnostic criteria for the interpretation of:

3.5.2.1A 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.

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

- Common carotid artery (CCA), external carotid artery (ECA), vertebral artery and subclavian artery 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.

*(See Guidelines on Page 20 for further recommendations.)*

### 3.6A Intracranial Cerebrovascular

3.6.1A For each intracranial cerebrovascular examination performed, there must be diagnostic criteria for the interpretation of:

3.6.1.1A grayscale images (if used);

3.6.1.2A spectral Doppler waveforms;

3.6.1.3A spectral Doppler velocities;

3.6.1.4A color Doppler images (if used).

### 3.7A Peripheral Arterial

3.7.1A For each peripheral arterial imaging examination (if performed), there must be diagnostic criteria for the interpretation of:

3.7.1.1A grayscale images;

- 3.7.1.2A spectral Doppler waveforms;
- 3.7.1.3A spectral Doppler velocities;
- 3.7.1.4A color Doppler images (if used).
- 3.7.2A For each of the following peripheral arterial non-imaging examinations (if performed), there must be diagnostic criteria for the interpretation of:
  - 3.7.2.1A ankle brachial index (ABI);
  - 3.7.2.2A segmental limb pressures (if used);
  - 3.7.2.3A continuous wave or pulsed wave Doppler waveforms;
  - 3.7.2.4A air plethysmographic waveforms (PVR);
  - 3.7.2.5A supplemental testing:
    - i. photoplethysmography signal amplitude and waveform;
    - ii. treadmill exercise/stress testing;
    - iii. abdominal aorta examination for aneurysm and/or stenosis.

### 3.8A Peripheral Venous

- 3.8.1A For each peripheral venous examination performed there must be diagnostic criteria for the interpretation of:
  - 3.8.1.1A grayscale images;
  - 3.8.1.2A spectral Doppler waveforms;
  - 3.8.1.3A spectral Doppler velocities;
  - 3.8.1.4A color Doppler images.
- 3.8.2A There must be diagnostic criteria for interpretation of:
  - 3.8.2.1A thrombosis and thrombus aging;
  - 3.8.2.2A patency;
  - 3.8.2.3A vein size;
  - 3.8.2.4A venous reflux in seconds/time;
  - 3.8.2.5A arteriovenous fistula (AVF) or dialysis access grafts;
  - 3.8.2.6A spectral Doppler velocities.

### 3.9A Visceral Vascular

- 3.9.1A For each visceral vascular examination performed there must be vessel specific diagnostic criteria for the interpretation of:
  - 3.9.1.1A grayscale images;

- 3.9.1.2A plaque morphology (when reported);
- 3.9.1.3A spectral Doppler waveforms;
- 3.9.1.4A spectral Doppler velocities (when required by the protocol);
- 3.9.1.5A color Doppler images (if used).

### 3.10A Screening

3.10.1A For each screening examination performed there must be diagnostic criteria for the interpretation of:

- 3.10.1.1A grayscale images;
- 3.10.1.2A spectral Doppler waveforms;
- 3.10.1.3A spectral Doppler velocities;
- 3.10.1.4A color Doppler images (if used).

3.10.2A Each screening examination must have specific reporting criteria.

3.10.2.1A Extracranial cerebrovascular screening:

- i. absence of disease, normal;
- ii. presence of disease with no overall significance;
- iii. presence of disease with overall significance;
- iv. occlusion.

3.10.2.2A Carotid intima-media thickness screening (CIMT):

- i. age, gender and race associated risk according to a standardized table of CIMT measurements should be used to generate a cardiovascular risk assessment report;
- ii. plaque characteristics and dimensions should be reported separately;
- iii. 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.

3.10.2.3A Peripheral arterial screening:

- i. absence of disease;
- ii. presence of disease;
- iii. non-diagnostic ABI.

3.10.2.4A Abdominal aorta aneurysm screening:

- i. absence of aneurysmal disease;
- ii. presence of aneurysmal disease;
- iii. aneurysmal status not defined due to non-visualization.

## **Section 3A: Examination Reports and Records**

### ***Guidelines***

- 3.2.6A *The final interpretation should address the clinical indications for the examination.*
- 3.5.2.1Ai *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).*

## Section 4A: Facility Safety

### STANDARD – Patient and Facility Safety

- 4.1A Patient safety must be ensured by written policies and procedures approved by the Medical Director.
- 4.1.1A A policy must be in place to address technical staff safety, comfort and avoidance of work-related musculoskeletal disorders (MSD).
- (See Guidelines below for further recommendations.)*
- 4.1.2A 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.
- 4.1.3A A written procedure must be documented with respect to:
- 4.1.3.1A control of infectious disease;
  - 4.1.3.2A transducer cleaning;
  - 4.1.3.3A protection of facility personnel from the transmission of infectious disease and blood borne pathogens.
- 4.1.4A Written procedures must be documented for handling acute medical emergencies and critically ill patients that includes:
- 4.1.4.1A appropriate equipment;
  - 4.1.4.2A supplies;
  - 4.1.4.3A trained personnel.
- 4.1.5A The facility must meet the Standards as set forth by the Occupational Safety and Health Administration (OSHA) and the Joint Commission (JC) where applicable.

## Section 4A: Facility Safety *Guidelines*

- 4.1.1A *Comment: For additional information regarding MSD, please visit:*  
[www.cdc.gov/niosh/docs/wp-solutions/2006-148/](http://www.cdc.gov/niosh/docs/wp-solutions/2006-148/)  
[www.sdms.org/OSHA/etool.asp](http://www.sdms.org/OSHA/etool.asp)  
[www.sdms.org/pdf/wrmsd2003.pdf](http://www.sdms.org/pdf/wrmsd2003.pdf)

## Section 5A: Administrative

### STANDARD – Patient Confidentiality

- 5.1A All facility 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

- 5.2A There must be a policy in place outlining the process for patients or other customers to issue a complaint/grievance in reference to the care/services they received at the facility and how the facility handles complaints/grievances.

### STANDARD – Primary Source Verification

- 5.3A There must be a policy in place identifying how the facility verifies the medical education, training, appropriate licenses and certifications of all physicians as well as the certification and training of all technical staff members and any other direct patient care providers.

## Section 5A: Administrative Guidelines

Sample documents are available for each of the required policies listed in Section 5A on the IAC Vascular Testing website at [intersocietal.org/vascular/seeking/sample\\_documents.htm](http://intersocietal.org/vascular/seeking/sample_documents.htm).

## Section 6A: Multiple Sites (Fixed and/or Mobile)

### STANDARD – Multiple Sites

- 6.1A When testing is performed at more than one physical facility, the facility may be eligible to apply for a single accreditation as a multiple site facility.
- 6.1.1A All facilities must have the same Medical Director.
- 6.1.2A All facilities must have the same Technical Director.
- 6.1.3A Supervision must be accomplished by one or more of the following:
- 6.1.3.1A the Technical Director works at each site two days per month;
- 6.1.3.2A every technical staff member from each multi-site works at the main facility two days each month;
- 6.1.3.3A an appropriately credentialed lead technologist is appointed at each multi-site facility and reports to the Technical Director.
- i. The lead technologist must:
- supervise and assist other technical staff members in performing examinations;
  - oversee the daily activities of the multi-site;
  - communicate weekly with the Technical Director to maintain compliance with these *Standards*.
- 6.1.4A Identical examination protocols must be utilized at all sites.
- 6.1.5A Identical diagnostic criteria must be utilized at all sites.
- 6.1.6A Quality Improvement (QI) must be performed at each site for all applicable testing areas.
- 6.1.7A Equipment of similar quality and capability must be utilized at all sites.

## Section 6A: Multiple Sites (Fixed and/or Mobile) *Guidelines*

*Facilities needing complete details on adding a multiple site should review the current IAC Policies and Procedures available on the IAC website at [intersocietal.org/iac/legal/policies.htm](http://intersocietal.org/iac/legal/policies.htm).*

# Part B:

## Examinations and Procedures

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### Section 1B: Extracranial Cerebrovascular Testing

#### STANDARD – Indications

- 1.1B Extracranial cerebrovascular testing must be performed for appropriate clinical indications
- 1.1.1B The indication for testing must be documented prior to performing the examination.
- (See Guidelines on Page 27 for further recommendations.)*

#### STANDARD – Equipment

- 1.2B Equipment must provide accurate data.
- 1.2.1B Imaging Equipment – Duplex ultrasound with color flow Doppler must be provided with:
- 1.2.1.1B imaging frequencies appropriate for the structures evaluated;
  - 1.2.1.2B Doppler frequencies appropriate for the vessels evaluated;
  - 1.2.1.3B range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest;
  - 1.2.1.4B a Doppler angle which is measurable and adjustable;
  - 1.2.1.5B a visual display and a permanent recording of the image;
  - 1.2.1.6B a visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.
- 1.2.2B Equipment Quality Control
- 1.2.2.1B Equipment used for diagnostic testing must be maintained in good operating condition.
  - 1.2.2.2B Equipment maintenance must include, but is not limited to:
    - i. record the method and frequency of maintenance of all imaging equipment;
    - ii. establishment of and adherence to a policy regarding routine safety inspections and testing of all facility electrical equipment;
    - iii. 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.

*(See Guidelines on Page 27 for further recommendations.)*

#### STANDARD – Protocols

- 1.3B Each examination performed in the facility must have a written protocol. The protocol must include:

- 1.3.1B equipment to be used for each examination;
- 1.3.2B elements of proper technique (also see [STANDARD – Techniques](#));
- 1.3.3B anatomic extent that constitutes a complete examination includes the evaluation of the entire course of the acceptable portion of each vessel:
  - 1.3.3.1B bilateral testing is considered a complete examination;
  - 1.3.3.2B variations in technique following vascular intervention;
  - 1.3.3.3B variations in technique and documentation for limited examinations.
- 1.3.4B 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](#));
- 1.3.5B a description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement grayscale imaging, spectral Doppler and velocity measurements.

*(See Guidelines on Page 27 for further recommendations.)*

## **STANDARD – Techniques**

- 1.4B 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.
  - 1.4.1B Elements of proper technique include, but are not limited to:
    - 1.4.1.1B performance of an examination according to the facility specific, written protocol;
    - 1.4.1.2B proper patient positioning;
    - 1.4.1.3B patient preparation;
    - 1.4.1.4B appropriate equipment and transducer selection;
    - 1.4.1.5B appropriate transducer positioning;
    - 1.4.1.6B proper sample volume size and positioning;
    - 1.4.1.7B optimization of equipment gain and display settings;
    - 1.4.1.8B a spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities;
    - 1.4.1.9B proper measurement of spectral velocities as required by the protocol;
    - 1.4.1.10B identification of vessels by imaging and Doppler.

## **STANDARD – Documentation**

- 1.5B Each examination performed in the facility must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:

- 1.5.1B grayscale images;
  - 1.5.2B color Doppler images;
  - 1.5.3B Doppler waveforms;
  - 1.5.4B velocity measurements;
  - 1.5.5B other images and waveforms as required by the protocol;
  - 1.5.6B other measurements as required by the protocol.
- 1.6B Abnormalities will require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.
- 1.6.1B Areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.
- 1.7B Extracranial Cerebrovascular Documentation
- 1.7.1B Long axis grayscale images must be documented as required by the protocol and must include at a minimum:
    - 1.7.1.1B common carotid artery;
    - 1.7.1.2B carotid artery bifurcation;
    - 1.7.1.3B internal carotid artery.
  - 1.7.2B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:
    - 1.7.2.1B proximal common carotid artery;
    - 1.7.2.2B mid/distal common carotid artery;
    - 1.7.2.3B proximal internal carotid artery;
    - 1.7.2.4B distal internal carotid artery (as distal as possible);
    - 1.7.2.5B one site in the external carotid artery;
    - 1.7.2.6B one site in the vertebral artery.
  - 1.7.3B Abnormalities require additional images, waveforms and velocity measurements.

## **STANDARD – Procedure Volumes**

- 1.8B Records must be maintained that permit evaluation of annual procedure volumes. These records must include:
  - 1.8.1B indication for the examination;
  - 1.8.2B technologist performing the examination;
  - 1.8.3B examination(s) performed;

- 1.8.4B examination findings;
- 1.8.5B physician interpreting the examination.

*(See [Guidelines below for further recommendations.](#))*

## **Section 1B: Extracranial Cerebrovascular Testing** *Guidelines*

- 1.1B *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.*
- 1.2.2.2B *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.*
- 1.3B *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.*
- 1.8B *The annual procedure volume should be sufficient to maintain proficiency in examination techniques and interpretation.*
  - *In general, a facility should perform a minimum of 100 complete examinations annually.*

## Section 2B: Intracranial Cerebrovascular Testing

### STANDARD – Indications

- 2.1B Intracranial cerebrovascular testing must be performed for appropriate clinical indications.
  - 2.1.1B The indication for testing must be documented prior to performing the examination.  
*(See Guidelines on Page 32 for further recommendations.)*

### STANDARD – Equipment

- 2.2B Equipment must provide accurate data.
  - 2.2.1B Imaging Equipment – Duplex ultrasound with color flow Doppler, if used for testing, must be provided with:
    - 2.2.1.1B imaging frequencies appropriate for the structures evaluated;
    - 2.2.1.2B Doppler frequencies appropriate for the vessels evaluated;
    - 2.2.1.3B range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest;
    - 2.2.1.4B a Doppler angle which is measurable and adjustable;
    - 2.2.1.5B a visual display and a permanent recording of the image;
    - 2.2.1.6B a visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.
  - 2.2.2B Continuous wave (CW) and pulsed wave (PW) Doppler, if used for testing, must be provided with:
    - 2.2.2.1B a direction sensitive Doppler blood flow meter;
    - 2.2.2.2B Doppler transducer frequencies appropriate for the vessels evaluated;
    - 2.2.2.3B Doppler waveform display demonstrating bidirectional flow and signal intensity;
    - 2.2.2.4B an audible output and a permanent recording of the waveform.
  - 2.2.3B Automated software packages (if used for testing such as automated emboli detection or calculators of hemodynamic indices) must be provided with:
    - 2.2.3.1B evidence of validation for the intended application.
  - 2.2.4B Equipment Quality Control
    - 2.2.4.1B Equipment used for diagnostic testing must be maintained in good operating condition.
    - 2.2.4.2B Equipment maintenance must include, but is not limited to:
      - i. record of the method and frequency of maintenance of all imaging equipment and non-imaging equipment;

- ii. establishment of and adherence to a policy regarding routine safety inspections and testing of all facility electrical equipment;
- iii. 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.

*(See Guidelines on Page 32 for further recommendations.)*

## **STANDARD – Protocols**

- 2.3B Each examination performed in the facility must have a written protocol. The protocol must include:
- 2.3.1B equipment to be used for each examination;
  - 2.3.2B elements of proper technique (also see [STANDARD – Techniques](#));
  - 2.3.3B anatomic extent that constitutes a complete examination includes the evaluation of the entire course of the accessible portion of each vessel;
  - 2.3.4B bilateral testing is considered a complete examination:
    - 2.3.4.1B anterior and posterior circulations including flow detection via temporal, orbital (when appropriate);
    - 2.3.4.2B foraminal and submandibular (when appropriate) windows must be described;
    - 2.3.4.3B variations in technique following vascular intervention;
    - 2.3.4.4B variations in technique and documentation for limited examinations.
  - 2.3.5B separate written protocols for additional intracranial cerebrovascular examinations (if performed) must include, but may not be limited to:
    - 2.3.5.1B emboli detection;
    - 2.3.5.2B vasomotor reactivity;
    - 2.3.5.3B right-to-left shunt;
    - 2.3.5.4B assessment of cerebral circulatory arrest;
    - 2.3.5.5B peri-procedural or intra-operative monitoring;
    - 2.3.5.6B monitoring of reperfusion therapies in acute stroke;
    - 2.3.5.7B monitoring in the neuro-intensive care setting.
  - 2.3.6B documentation that must be acquired for normal exams and the additional documentation that must be acquired to describe abnormalities, if present (also see [STANDARD – Documentation](#));
  - 2.3.7B a description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement grayscale imaging, spectral Doppler and velocity measurements;
  - 2.3.8B depth ranges for each vessel segment in adults and children (when appropriate);
  - 2.3.9B extent of power reduction to be used for transorbital examinations.

- 2.3.9.1B For patient safety, the output power must not exceed 10% of maximum emitted power or 17 mW per cm<sup>2</sup> or equivalent measurements.

*(See Guidelines on Page 32 for further recommendations.)*

## **STANDARD – Techniques**

- 2.4B 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.
  - 2.4.1B Elements of proper technique include, but are not limited to:
    - 2.4.1.1B performance of an examination according to the written, facility specific protocol;
    - 2.4.1.2B proper patient positioning;
    - 2.4.1.3B patient preparation;
    - 2.4.1.4B appropriate equipment and transducer selection;
    - 2.4.1.5B appropriate transducer positioning;
    - 2.4.1.6B proper sample volume size, depth and positioning;
    - 2.4.1.7B optimization of equipment gain and display settings;
    - 2.4.1.8B spectral Doppler angle and placement as required by the protocol;
    - 2.4.1.9B proper measurement of spectral velocities as required by the protocol;
    - 2.4.1.10B identification of vessels by imaging and Doppler.

*(See Guidelines on Page 32 for further recommendations.)*

## **STANDARD – Documentation**

- 2.5B Each examination performed in the facility must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:
  - 2.5.1B grayscale images (if imaging used);
  - 2.5.2B color Doppler images (if imaging used);
  - 2.5.3B Doppler waveforms;
  - 2.5.4B velocity measurements;
  - 2.5.5B other images (if used) and waveforms as required by the protocol;
  - 2.5.6B other measurements as required by the protocol.
- 2.6B Abnormalities will require additional images (if imaging used) and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.
  - 2.6.1B Areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.

## 2.7B Intracranial Cerebrovascular Documentation

- 2.7.1B Spectral Doppler waveforms, velocity measurements, flow direction and signal intensity must be documented as required by the protocol and must include at a minimum:
- 2.7.1.1B proximal M1 middle cerebral artery MCA;
  - 2.7.1.2B A1 anterior cerebral artery (ACA);
  - 2.7.1.3B cross-filling via anterior communicating artery (when detectable);
  - 2.7.1.4B terminal internal carotid artery (TICA);
  - 2.7.1.5B collateral flow via posterior communicating artery (when detectable);
  - 2.7.1.6B P1 or P2 posterior cerebral artery (PCA);
  - 2.7.1.7B ophthalmic artery (when appropriate);
  - 2.7.1.8B internal carotid artery (ICA) siphon;
  - 2.7.1.9B terminal vertebral artery (VA);
  - 2.7.1.10B proximal and distal basilar artery;
  - 2.7.1.11B distal ICA segment at the entrance to the skull (when appropriate).
- 2.7.2B Depth ranges for these segments in adults and children (when appropriate) must be documented.
- 2.7.3B Abnormalities require additional images, waveforms and velocity measurements.

## **STANDARD – Procedure Volumes**

- 2.8B Records must be maintained that permit evaluation of annual procedure volumes. These records must include:
- 2.8.1B indication for the examination;
  - 2.8.2B technologist performing the examination;
  - 2.8.3B examination(s) performed;
  - 2.8.4B examination findings;
  - 2.8.5B physician interpreting the examination.

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

## Section 2B: Intracranial Cerebrovascular Testing *Guidelines*

2.1B *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.*

2.2.4.2B *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.*

2.3B *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.*

2.4.1B *Headgear for monitoring transducer fixation should be used (when appropriate).*

2.8B *The annual procedure volume should be sufficient to maintain proficiency in examination techniques and interpretation.*

- *In general, a facility should perform a minimum of 100 complete examinations annually.*

## Section 3B: Peripheral Arterial Testing

### STANDARD – Indications

- 3.1B Peripheral arterial testing must be performed for appropriate clinical indications.
  - 3.1.1B The indication for testing must be documented prior to performing the examination.  
*(See Guidelines on Page 40 for further recommendations.)*

### STANDARD – Equipment

- 3.2B Equipment must provide accurate data.
  - 3.2.1B Imaging Equipment – Duplex ultrasound with color flow Doppler, if used for testing, must be provided with:
    - 3.2.1.1B imaging frequencies appropriate for the structures evaluated;
    - 3.2.1.2B Doppler frequencies appropriate for the vessels evaluated;
    - 3.2.1.3B range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest;
    - 3.2.1.4B a Doppler angle which is measurable and adjustable;
    - 3.2.1.5B a visual display and a permanent recording of the image;
    - 3.2.1.6B a visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.
  - 3.2.2B Continuous wave (CW) and pulsed wave (PW) Doppler, if used for testing, must be provided with:
    - 3.2.2.1B a direction sensitive Doppler blood flow meter;
    - 3.2.2.2B Doppler transducer frequencies appropriate for the vessels evaluated;
    - 3.2.2.3B Doppler waveform display demonstrating bidirectional flow;
    - 3.2.2.4B an audible output and a permanent recording of the waveform.
  - 3.2.3B Segmental limb plethysmography, if used for testing, must be provided with:
    - 3.2.3.1B equipment capable of measuring small segmental volume changes and providing permanent recordings;
    - 3.2.3.2B cuffs of varying sizes appropriate to the technique and the limb segment to be evaluated.
  - 3.2.4B Supplemental Equipment
    - 3.2.4.1B Photoplethysmography (PPG), if used for testing, must be provided with:
      - i. appropriate electrical coupling for signal display;
      - ii. capability of providing a permanent recording of the waveform.

3.2.4.2B Limb air plethysmography (pulse volume recording-PVR ), if used for testing, must be provided with:

- i. appropriately sized pneumatic cuffs;
- ii. capability of being calibrated before each examination;
- iii. capability of measuring small limb volume changes;
- iv. capability of providing a permanent recording of the data.

3.2.4.3B Treadmill exercise/stress testing, if used for testing, must be provided with:

- i. motor-driven treadmill capable of providing constant speed and inclination.

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

Comment: If additional examinations are performed and additional testing equipment is utilized and is not listed here, a written protocol, diagnostic criteria and quality improvement methods must be in place and available for review upon request.

### 3.2.5B Equipment Quality Control

3.2.5.1B Equipment used for diagnostic testing must be maintained in good operating condition.

3.2.5.2B Equipment maintenance must include, but is not limited to:

- i. record of the method and frequency of maintenance of all imaging equipment and non-imaging equipment;
- ii. establishment of and adherence to a policy regarding routine safety inspections and testing of all facility electrical equipment;
- iii. 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.

*([See Guidelines on Page 40 for further recommendations.](#))*

## **STANDARD – Protocols**

3.3B Each examination performed in the facility must have a written protocol. The protocol must include:

3.3.1B equipment to be used for each examination;

3.3.2B elements of proper technique (also see [STANDARD – Techniques](#));

3.3.3B anatomic extent that constitutes a complete examination includes evaluation of the entire course of the accessible portion of each vessel:

3.3.3.1B bilateral testing is considered a complete examination;

3.3.3.2B variations in technique following vascular intervention;

3.3.3.3B variations in technique and documentation for limited examinations must be described.

3.3.4B the performance of an ankle brachial index (ABI);

3.3.5B the acquisition of waveforms (either CW or PW or PVR) from at least three levels;

- 3.3.6B the measurement of systolic blood pressure at more than one level if indicated;
- 3.3.7B 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](#));
- 3.3.8B a description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement grayscale imaging, spectral Doppler and velocity measurements.

*(See Guidelines on Page 40 for further recommendations.)*

## **STANDARD – Techniques**

- 3.4B 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.
  - 3.4.1B Examinations must include:
    - 3.4.1.1B Performance of an ABI.
      - i. 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.
      - ii. 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.
    - 3.4.1.2B 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.
  - 3.4.2B Elements of proper technique include, but are not limited to:
    - 3.4.2.1B performance of an examination according to the facility specific, written protocol;
    - 3.4.2.2B proper patient positioning;
    - 3.4.2.3B patient preparation;
    - 3.4.2.4B appropriate equipment and transducer selection;
    - 3.4.2.5B appropriate transducer positioning;
    - 3.4.2.6B proper sample volume size and positioning;
    - 3.4.2.7B optimization of equipment gain and display settings;
    - 3.4.2.8B a spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities;
    - 3.4.2.9B proper measurement of spectral velocities as required by the protocol;
    - 3.4.2.10B identification of vessels by imaging and Doppler.

## STANDARD – Documentation

3.5B Each examination performed in the facility must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:

3.5.1B Ankle brachial index (ABI):

3.5.1.1B 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:

- i. the ABI is performed within two weeks prior to the duplex examination;
- ii. was performed in the same facility;
- iii. there has been no change in the patient's symptoms;
- iv. the results and date of the previous ABI must be included in the final report.

3.5.1.2B CW Doppler or PW Doppler or PVR waveforms.

3.5.2B grayscale images;

3.5.3B color Doppler images;

3.5.4B Doppler waveforms;

3.5.5B velocity measurements;

3.5.6B other images if used and waveforms as required by the protocol;

3.5.7B other measurements as required by the protocol.

3.6B Abnormalities will require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.

3.6.1B Areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.

3.7B Peripheral Arterial Documentation

3.7.1B Duplex ultrasound of lower extremity arteries (if performed) must include:

3.7.1.1B Long axis grayscale images and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

- i. common femoral artery;
- ii. superficial femoral artery;
- iii. proximal deep femoral artery;
- iv. popliteal artery;
- v. aorta, common and external iliac arteries and tibial arteries (when appropriate);
- vi. bypass graft(s) when present including anastomoses.

3.7.1.2B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- i. common femoral artery;
- ii. superficial femoral artery;
- iii. proximal deep femoral artery;

- iv. popliteal artery;
  - v. tibial arteries;
  - vi. aorta, common and external iliac arteries (when appropriate);
  - vii. bypass graft when present, including proximal and distal anastomoses, inflow and outflow arteries.
- 3.7.1.3B Abnormalities require additional images, waveforms and velocity measurements.
- 3.7.2B Duplex ultrasound of upper extremity arteries (if performed) must include:
  - 3.7.2.1B Long axis grayscale images and/or color Doppler images must be documented as required by the protocol and must include at a minimum:
    - i. subclavian artery;
    - ii. axillary artery;
    - iii. brachial artery;
    - iv. innominate and forearm arteries (when appropriate);
    - v. bypass graft(s) when present including anastomoses.
  - 3.7.2.2B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:
    - i. subclavian artery;
    - ii. axillary artery;
    - iii. brachial artery;
    - iv. radial and ulnar arteries;
    - v. innominate artery (when appropriate);
    - vi. bypass graft when present, including proximal and distal anastomoses, inflow and outflow arteries.
  - 3.7.2.3B Abnormalities require additional images, waveforms and velocity measurements.
- 3.8B Non-imaging (physiologic) examinations (if performed) must include bilateral sampling from three or more levels. **Only one type of waveform is required (CW Doppler or PW Doppler or PVR).**
- 3.8.1B **Doppler waveforms (either CW or PW) must be documented as required by the protocol and must include at a minimum:**
  - 3.8.1.1B common femoral artery;
  - 3.8.1.2B popliteal artery;
  - 3.8.1.3B distal tibial arteries at the level of the ankle.
- 3.8.2B Plethysmographic waveforms must be documented from:
  - 3.8.2.1B thigh;
  - 3.8.2.2B calf;
  - 3.8.2.3B ankle;
  - 3.8.2.4B toe waveforms (if indicated);
  - 3.8.2.5B toe systolic pressures (if indicated).

3.9B 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.

3.9.1B Photoplethysmography (if performed) must be documented as required by the protocol and must include at a minimum:

3.9.1.1B documentation of the digital waveforms.

3.9.2B Treadmill exercise/stress testing, if performed, must be documented as required by the protocol and must include at a minimum:

3.9.2.1B pressures obtained at rest;

3.9.2.2B pressures obtained at timed intervals immediately after exercise;

3.9.2.3B for treadmill-based protocols, the time of onset of claudication and maximal walking time.

3.9.3B Abdominal aorta examinations (if performed) must be documented as required by the protocol and must include at a minimum:

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

3.9.3.1B Transverse view (defined as perpendicular to the long axis of the aorta) grayscale images with the single widest outer wall to outer wall diameter measurement must be documented as required by the protocol and must include at a minimum:

- i. proximal aorta;
- ii. mid aorta;
- iii. distal aorta;
- iv. common iliac arteries at the bifurcation.

3.9.3.2B Long axis grayscale images must be documented as required by the protocol and must include at a minimum:

- i. proximal aorta;
- ii. mid aorta;
- iii. distal aorta;
- iv. documentation of aneurysms (if present) must include the widest size of the aorta measured outer wall to outer wall;
- v. additional images proximal and distal to the aneurysm.

3.9.3.3B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- i. aorta at/or proximal to the renal artery origins;
- ii. mid aorta;
- iii. distal aorta;
- iv. right common iliac artery;
- v. left common iliac artery.

*(See Guidelines on Page 40 for further recommendations.)*

- 3.9.3.4B Abnormalities require additional images, waveforms and velocity measurements.
- 3.9.4B Arteriovenous fistula (AVF)/dialysis access grafts, if performed, must be documented as required by the protocol and must include at a minimum:
  - 3.9.4.1B A description of the type of fistula or graft.
  - 3.9.4.2B Long axis grayscale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:
    - i. inflow artery proximal to graft or fistula;
    - ii. anastomotic site(s);
    - iii. outflow vein;
    - iv. axillary and subclavian veins (when appropriate).
  - 3.9.4.3B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:
    - i. inflow artery;
    - ii. proximal and distal anastomoses (graft);
    - iii. anastomosis site (fistula);
    - iv. outflow vein beyond anastomosis.
  - 3.9.4.4B If evaluation includes provocative maneuvers for steal phenomenon, digital image documentation of findings with and without maneuvers.  
  
 Comment: Spectral Doppler imaging of the ipsilateral axillary and subclavian veins should be obtained to document proximal patency.
  - 3.9.4.5B Abnormalities require additional images, waveforms and velocity measurements.

## STANDARD – Procedure Volumes

- 3.10B Records must be maintained that permit evaluation of annual procedure volumes. These records must include:
  - 3.10.1B indication for the examination;
  - 3.10.2B technologist performing the examination;
  - 3.10.3B examination(s) performed;
  - 3.10.4B examination findings;
  - 3.10.5B physician interpreting the examination.

*(See Guidelines on Page 40 for further recommendations.)*

## Section 3B: Peripheral Arterial Testing *Guidelines*

3.1B *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.*

3.2.5.2B *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.*

3.3B *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.*

3.9.3.3B *Color Doppler images may supplement grayscale imaging but does not substitute for it.*

3.10B *The annual procedure volume should be sufficient to maintain proficiency in exam techniques and interpretation.*

- *In general, a facility should perform a minimum of 100 complete examinations annually.*

# Section 4B: Peripheral Venous Testing

## STANDARD – Indications

- 4.1B Peripheral venous testing must be performed for appropriate clinical indications.
- 4.1.1B The indication for testing must be documented prior to performing the examination.
- (See Guidelines on Page 47 for further recommendations.)*

## STANDARD – Equipment

- 4.2B Equipment must provide accurate data.
- 4.2.1B Imaging Equipment – Duplex ultrasound with color flow Doppler must be provided with:
- 4.2.1.1B imaging frequencies appropriate for the structures evaluated;
  - 4.2.1.2B Doppler frequencies appropriate for the vessels evaluated;
  - 4.2.1.3B range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest;
  - 4.2.1.4B a Doppler angle which is measurable and adjustable;
  - 4.2.1.5B a visual display and a permanent recording of the image;
  - 4.2.1.6B a visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.
- 4.2.2B Equipment Quality Control
- 4.2.2.1B Equipment used for diagnostic testing must be maintained in good operating condition.
  - 4.2.2.2B Equipment maintenance must include, but is not limited to:
    - i. record the method and frequency of maintenance of all imaging equipment and;
    - ii. establishment of and adherence to a policy regarding routine safety inspections and testing of all facility electrical equipment;
    - iii. 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.

*(See Guidelines on Page 47 for further recommendations.)*

## STANDARD – Protocols

- 4.3B Each examination performed in the facility must have a written protocol. The protocol must include:
- 4.3.1B equipment to be used for each examination;
  - 4.3.2B elements of proper technique (also see [STANDARD – Techniques](#));

- 4.3.3B anatomic extent that constitutes a complete examination includes evaluation of the entire course of the accessible portion of each vessel:
- 4.3.3.1B variations in technique following vascular interventions, including dialysis access;
  - 4.3.3.2B variations in technique and documentation for limited exams.
- 4.3.4B 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](#));
- 4.3.5B a description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement grayscale imaging and spectral Doppler measurements.

*(See Guidelines on Page 47 for further recommendations.)*

## **STANDARD – Techniques**

- 4.4B Appropriate techniques must be used for the evaluation of the peripheral venous system, stents, arteriovenous fistula (AVF) / dialysis access grafts to assess for the presence of any abnormalities and to document their severity, location, extent and whenever possible etiology.
- 4.4.1B Elements of proper technique include, but are not limited to:
- 4.4.1.1B performance of an examination according to the facility specific, written protocol;
  - 4.4.1.2B proper patient positioning;
    - i. for assessing reflux: standing, sitting or reverse Trendelenburg (at least 15 degrees) must be used to maintain lower extremity dependency.
  - 4.4.1.3B patient preparation;
  - 4.4.1.4B appropriate equipment and transducer selection;
  - 4.4.1.5B appropriate transducer positioning;
  - 4.4.1.6B proper sample volume size and positioning;
  - 4.4.1.7B optimization of equipment gain and display settings;
  - 4.4.1.8B proper measurements as required by the protocol:
    - i. **vein diameter measurements must:**
      - be acquired with the extremity(s) in a dependent position;
      - be measured anterior outer wall to posterior outer wall;
      - assure that no external pressure is applied to the vein.
  - 4.4.1.9B identification of vessels by imaging and Doppler;
  - 4.4.1.10B transverse grayscale imaging without and with transducer compressions;
  - 4.4.1.11B long axis spectral Doppler evaluation with or without color imaging.

## STANDARD – Documentation

4.5B Each examination performed in the facility must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:

4.5.1B grayscale images;

4.5.2B color Doppler images;

4.5.3B Doppler waveforms;

4.5.4B velocity measurements;

4.5.5B other images and waveforms as required by the protocol;

4.5.6B other measurements as required by the protocol.

4.6B Abnormalities will require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology.

4.6.1B Areas of suspected obstruction must include representative Doppler waveforms recorded at and distal to the obstruction.

4.7B Peripheral Venous Documentation

4.7.1B Lower Extremity Venous Duplex for Thrombosis and Patency

4.7.1.1B Transverse grayscale images without and with transducer compressions (when anatomically possible or not contraindicated) must be documented as required by the protocol and must include at a minimum:

- i. common femoral vein;
- ii. saphenofemoral junction;
- iii. proximal femoral vein;
- iv. mid femoral vein;
- v. distal femoral vein;
- vi. popliteal vein;
- vii. posterior tibial veins;
- viii. peroneal veins;
- ix. additional images to document areas of suspected thrombus;
- x. additional images (if required by the facility protocol).

*(See Guidelines on Page 47 for further recommendations.)*

4.7.1.2B Spectral Doppler waveforms demonstrating spontaneous venous flow, phasicity and/or flow augmentation must be documented as required by the protocol and must include at a minimum:

- i. right and left common femoral veins;
- ii. popliteal vein;
- iii. additional waveforms if required by the facility protocol.

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

*(See Guidelines on Page 47 for further recommendations.)*

4.7.1.3B Abnormalities require additional images, waveforms and velocity measurements.

4.7.2B Lower Extremity Venous Duplex for Reflux

4.7.2.1B Transverse grayscale images without and with transducer compressions (when anatomically possible or not contraindicated) must be documented as required by the protocol and must include at a minimum:

- i. common femoral vein;
- ii. saphenofemoral junction;
- iii. mid femoral vein;
- iv. great saphenous vein;
- v. popliteal vein;
- vi. small saphenous vein.

*(See Guidelines on Page 47 for further recommendations.)*

4.7.2.2B Spectral Doppler waveforms with the extremity(s) in a dependent position, demonstrating baseline flow and response to distal augmentation and if reflux is present, duration of retrograde flow measured with calipers and documented as required by the protocol and must include at a minimum:

- i. common femoral vein;
- ii. saphenofemoral junction;
- iii. great saphenous vein;
- iv. mid femoral vein;
- v. popliteal vein;
- vi. small saphenous vein.

*(See Guidelines on Page 47 for further recommendations.)*

4.7.2.3B Transverse grayscale images of diameter measurement must be documented as required by the protocol and must include at a minimum:

- i. saphenofemoral junction;
- ii. great saphenous vein at proximal thigh;
- iii. great saphenous vein at knee;
- iv. small saphenous vein (at saphenopopliteal junction).

4.7.3B Upper Extremity Venous Duplex for Thrombosis and Patency

4.7.3.1B Transverse grayscale images without and with transducer compressions (when anatomically possible or not contraindicated) must be documented as required by the protocol and must include at a minimum:

- i. internal jugular vein;
- ii. subclavian vein;
- iii. axillary vein;
- iv. brachial vein(s);
- v. basilic vein;
- vi. cephalic vein;
- vii. additional images to document areas of suspected thrombus;
- viii. additional images if required by the facility protocol.

*(See Guidelines on Page 47 for further recommendations.)*

4.7.3.2B Spectral Doppler waveforms demonstrating spontaneous venous flow, phasicity and/or flow augmentation must be documented as required by the protocol and must include at a minimum:

- i. internal jugular vein;
- ii. right and left subclavian veins;
- iii. axillary vein;
- iv. additional waveforms if required by the facility protocol.

Comment: For unilateral examinations, spectral Doppler waveforms must be documented from the right and left subclavian vein.

*(See Guidelines on Page 47 for further recommendations.)*

4.7.4B Vein mapping, if performed, must include:

4.7.4.1B assessment of the veins required by the facility protocol;

4.7.4.2B vein patency and size.

4.7.5B Venous stents (if present) must include **at a minimum**:

4.7.5.1B **Spectral Doppler waveforms with color Doppler images as required by the protocol and must include at a minimum:**

- i. **proximal stent;**
- ii. **mid stent;**
- iii. **distal stent;**
- iv. **native vessel adjacent to the proximal end of the stent;**
- v. **native vessel adjacent to distal end of the stent.**

4.7.6B **Arteriovenous fistula (AVF)/dialysis access grafts, if performed, must be documented as required by the protocol and must include at a minimum:**

4.7.6.1B **A description of the type of fistula or graft.**

4.7.6.2B **Long axis grayscale images and/or color Doppler images must be documented as required by the protocol and must include at a minimum:**

- i. **inflow artery proximal to graft or fistula;**
- ii. **anastomotic site(s);**
- iii. **outflow vein;**
- iv. **axillary and subclavian veins (when appropriate).**

4.7.6.3B **Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:**

- i. **inflow artery;**
- ii. **proximal and distal anastomoses (graft);**
- iii. **anastomosis site (fistula);**
- iv. **outflow vein beyond anastomosis.**

4.7.6.4B **If evaluation includes provocative maneuvers for steal phenomenon, digital image documentation of findings with and without maneuvers.**

**Comment: Spectral Doppler imaging of the ipsilateral axillary and subclavian veins should be obtained to document proximal patency.**

4.7.6.5B **Abnormalities require additional images, waveforms and velocity measurements.**

## **STANDARD – Procedure Volumes**

4.8B Records must be maintained that permit evaluation of annual procedure volumes. These records must include:

- 4.8.1B indication for the examination;
- 4.8.2B technologist performing the examination;
- 4.8.3B examination(s) performed;
- 4.8.4B examination findings;
- 4.8.5B physician interpreting the examination.

*[\(See Guidelines on Page 47 for further recommendations.\)](#)*

## Section 4B: Peripheral Venous Testing Guidelines

- 4.1B *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.*
- 4.2.2.2B *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.*
- 4.3B *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.*
- 4.7.1.1B *Additional sites may be required by the facility 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.*
- *When indicated or required by the facility’s written protocol, vein size measurements must be recorded.*
- 4.7.1.2B, 4.7.2.1B *Additional sites may be required by the facility protocol or when indicated – common iliac, external iliac, proximal deep femoral, deep calf, or perforating veins or inferior vena cava.*
- 4.7.2.2B *Additional sites may be required by the facility protocol or when indicated – common iliac, external iliac, proximal deep femoral, deep calf, perforating veins or other accessory venous tributaries, inferior vena cav.*
- 4.7.3.1B *Additional sites may be required by the facility protocol or when indicated – jugular/subclavian vein junction, brachiocephalic (innominate) vein or forearm veins.*
- *When indicated or required by the facility’s written protocol, vein size measurements must be recorded.*
- 4.7.3.2B *Additional sites may be required by the facility protocol or when indicated – jugular/subclavian confluence, brachiocephalic (innominate) vein, brachial vein, basilic vein, cephalic vein or forearm veins.*
- 4.8B *The annual procedure volume should be sufficient to maintain proficiency in examination techniques and interpretation.*
- *In general, a facility should perform a minimum of 100 complete examinations annually.*

# Section 5B: Visceral Vascular Testing

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## STANDARD – Indications

5.1B Visceral vascular testing must be performed for appropriate clinical indications.

5.1.1B The indication for testing must be documented prior to performing the examination.

*(See Guidelines on Page 54 for further recommendations.)*

## STANDARD – Equipment

5.2B Equipment must provide accurate data.

5.2.1B Imaging Equipment – Duplex ultrasound with color flow Doppler must be provided with:

5.2.1.1B imaging frequencies appropriate for the structures evaluated;

5.2.1.2B Doppler frequencies appropriate for the vessels evaluated;

5.2.1.3B range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest;

5.2.1.4B a Doppler angle which is measurable and adjustable;

5.2.1.5B a visual display and a permanent recording of the image;

5.2.1.6B a visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.

5.2.2B Equipment Quality Control

5.2.2.1B Equipment used for diagnostic testing must be maintained in good operating condition.

5.2.2.2B Equipment maintenance must include, but is not limited to:

- i. record the method and frequency of maintenance of all imaging equipment;
- ii. establishment of and adherence to a policy regarding routine safety inspections and testing of all facility electrical equipment;
- iii. 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.

*(See Guidelines on Page 54 for further recommendations.)*

## STANDARD – Protocols

5.3B Each examination performed in the facility must have a written protocol. The protocol must include:

5.3.1B the equipment to be used for each examination;

5.3.2B the elements of proper technique (also see [STANDARD – Techniques](#));

- 5.3.3B anatomic extent that constitutes a complete examination includes evaluation of the entire course of the accessible portion of each vessel:
  - 5.3.3.1B variations in technique following vascular intervention;
  - 5.3.3.2B variations in technique and documentation for 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.

- 5.3.4B 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](#));
- 5.3.5B a description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement grayscale imaging, spectral Doppler and velocity measurements.

*(See Guidelines on Page 54 for further recommendations.)*

- 5.4B Visceral vascular examinations comprise the following visceral vascular systems:
  - 5.4.1B mesenteric arterial system;
  - 5.4.2B hepatoportal system;
  - 5.4.3B renal vasculature;
  - 5.4.4B renal transplant;
  - 5.4.5B liver transplant.
- 5.5B Visceral vascular testing comprises several distinct examinations because different indications require specific vascular systems to be evaluated.
  - 5.5.1B Each visceral vascular system requires several vessels to be examined.
  - 5.5.2B Some examinations also require grayscale imaging of the appropriate organ.

## **STANDARD – Techniques**

- 5.6B 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.
  - 5.6.1B Elements of proper technique include, but are not limited to:
    - 5.6.1.1B performance of an examination according to the facility specific, written protocol;
    - 5.6.1.2B proper patient positioning;
    - 5.6.1.3B patient preparation;
    - 5.6.1.4B appropriate equipment and transducer selection;
    - 5.6.1.5B appropriate transducer positioning;
    - 5.6.1.6B proper sample volume size and positioning;

- 5.6.1.7B optimization of equipment gain and display settings;
- 5.6.1.8B a spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities;
- 5.6.1.9B proper measurement of spectral velocities as required by the protocol;
- 5.6.1.10B identification of vessels by imaging and Doppler.

## **STANDARD – Documentation**

- 5.7B Each examination performed in the facility must provide documentation as required by the protocol that is sufficient to allow proper interpretation, including but not limited to:
  - 5.7.1B grayscale images;
  - 5.7.2B color Doppler images;
  - 5.7.3B Doppler waveforms;
  - 5.7.4B velocity measurements;
  - 5.7.5B other images and waveforms as required by the protocol;
  - 5.7.6B other measurements as required by the protocol.
- 5.8B Abnormalities will require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.
  - 5.8.1B Documentation areas of suspected stenosis or obstruction must include representative Doppler waveforms and velocity measurements recorded at and distal to the stenosis or obstruction.
- 5.9B Visceral Vascular Documentation
  - 5.9.1B Mesenteric Arterial System
    - 5.9.1.1B Grayscale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:
      - i. adjacent aorta to celiac or superior mesenteric artery;
      - ii. celiac artery;
      - iii. superior mesenteric artery;
      - iv. inferior mesenteric artery.
    - 5.9.1.2B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:
      - i. adjacent aorta;
      - ii. celiac artery origin;
      - iii. hepatic artery (does not require velocity measurements);
      - iv. superior mesenteric artery origin;
      - v. proximal superior mesenteric artery (beyond the origin);
      - vi. inferior mesenteric artery.

## 5.9.2B Hepatoportal System

5.9.2.1B Grayscale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

- i. intrahepatic portal vein;
- ii. extrahepatic portal vein;
- iii. hepatic veins;
- iv. inferior vena cava;
- v. adjacent liver parenchyma;
- vi. portosystemic shunts or collateral pathways (when present).

5.9.2.2B Spectral Doppler waveforms must be documented as required by the protocol and must include at a minimum:

- i. common portal vein;
- ii. right portal vein;
- iii. left portal vein;
- iv. superior mesenteric vein;
- v. splenic vein;
- vi. right, left and middle hepatic veins;
- vii. inferior vena cava;
- viii. portosystemic shunts (when present).

5.9.2.3B 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:

- i. portal vein inflow;
- ii. left and right portal veins (does not require velocity measurements);
- iii. portal end stent;
- iv. mid stent;
- v. hepatic end stent;
- vi. hepatic vein outflow (does not require velocity measurements).

## 5.9.3B Renal Vasculature

5.9.3.1B Grayscale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

- i. aorta at the level of the renal arteries;
- ii. renal arteries;
- iii. renal artery and vein at the hilum;
- iv. grayscale pole to pole renal length measurements.

5.9.3.2B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- i. aorta at the level of the renal arteries;
- ii. origin/ostia of the renal artery;
- iii. proximal main renal artery;
- iv. mid main renal artery;
- v. distal main renal artery;
- vi. parenchymal/hilar arteries (when appropriate);
- vii. accessory renal artery (when present);
- viii. renal veins, when appropriate (does not require velocity measurements).

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

#### 5.9.4B Renal Transplant

5.9.4.1B Grayscale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

- i. transplant renal artery;
- ii. transplant renal vein;
- iii. grayscale images of transplant kidney and peri-transplant region.

5.9.4.2B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- i. donor artery;
- ii. region of arterial anastomosis;
- iii. proximal transplant renal artery;
- iv. distal transplant renal artery;
- v. **parenchyma/hilar arteries;**
- vi. transplant renal vein (does not require velocity measurements);
- vii. renal vein **at or near** anastomosis (does not require velocity measurements).

#### 5.9.5B Liver Transplant

5.9.5.1B Grayscale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:

- i. **color Doppler of intrahepatic portal vein;**
- ii. **color Doppler of extrahepatic portal vein;**
- iii. **color Doppler of hepatic veins;**
- iv. **color Doppler of the left and right portal veins;**
- v. **hepatic artery;**
- vi. inferior vena cava;
- vii. grayscale images of transplant liver and peri-transplant region.

5.9.5.2B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- i. donor **hepatic artery in the region of the anastomosis;**
- ii. hepatic artery;
- iii. **left and right hepatic arteries (does not require velocity measurements);**
- iv. hepatic veins (does not require velocity measurements);
- v. portal vein anastomosis;
- vi. portal vein;
- vii. inferior vena cava (does not require velocity measurements).

5.9.6B Abdominal aorta examinations (if performed) must be documented as required by the protocol and must include at a minimum.

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

5.9.6.1B Transverse view (defined as perpendicular to the long axis of the aorta) grayscale images with the single widest outer wall to outer wall diameter measurement must be documented as required by the protocol and must include at a minimum:

- i. proximal aorta;
- ii. mid aorta;
- iii. distal aorta;
- iv. common iliac arteries at the bifurcation.

5.9.6.2B Long axis grayscale images must be documented as required by the protocol and must include at a minimum:

- i. proximal aorta;
- ii. mid aorta;
- iii. distal aorta;
- iv. documentation of aneurysms (if present) must include the widest size of the aorta measured outer wall to outer wall. Additional images proximal and distal to the aneurysm must be recorded.

5.9.6.3B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- i. aorta at/or proximal to the renal artery origins;
- ii. mid aorta;
- iii. distal aorta;
- iv. right common iliac artery;
- v. left common iliac artery.

*(See Guidelines on Page 54 for further recommendations.)*

## **STANDARD – Procedure Volumes**

5.10B Records must be maintained that permit evaluation of annual procedure volumes. These records must include:

- 5.10.1B indication for the examination;
- 5.10.2B technologist performing the examination;
- 5.10.3B examination(s) performed;
- 5.10.4B examination findings;
- 5.10.5B the physician interpreting the examination.

*(See Guidelines on Page 54 for further recommendations.)*

## Section 5B: Visceral Vascular Testing *Guidelines*

5.1B *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.*

5.2.2.2B *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.*

5.3B *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.*

5.9.6.3B *Color Doppler images may supplement grayscale imaging but does not substitute for it.*

5.10B *The annual procedure volume should be sufficient to maintain proficiency in examination techniques and interpretation.*

- *In general, a facility should perform a minimum of 100 complete examinations annually.*

# Section 6B: Screening Testing

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

## STANDARD – Indications

- 6.1B 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.
  - 6.1.1B Screening guidelines for the appropriate selection of participants should be based upon contemporary scientific publications.
  - 6.1.2B Screening cannot replace diagnostic examinations for symptomatic individuals.

## STANDARD – Equipment

- 6.2B Equipment must provide accurate data.
  - 6.2.1B Imaging Equipment – Duplex ultrasound with color flow Doppler must be provided with:
    - 6.2.1.1B imaging frequencies appropriate for the structures evaluated;
    - 6.2.1.2B Doppler frequencies appropriate for the vessels evaluated;
    - 6.2.1.3B range-gated spectral Doppler with the ability to adjust the depth and position of the range gate within the area of interest;
    - 6.2.1.4B a Doppler angle which is measurable and adjustable;
    - 6.2.1.5B a visual display and a permanent recording of the image;
    - 6.2.1.6B a visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle.
  - 6.2.2B Continuous wave (CW) and pulsed wave (PW) Doppler, if used for testing, must be provided with:
    - 6.2.2.1B a direction sensitive Doppler blood flow meter;
    - 6.2.2.2B Doppler transducer frequencies appropriate for the vessels evaluated;
    - 6.2.2.3B Doppler waveform display demonstrating bidirectional flow;
    - 6.2.2.4B an audible output and a permanent recording of the waveform;
    - 6.2.2.5B cuffs of varying widths appropriate to the limb segment to be evaluated.
  - 6.2.3B Computerized assisted electronic calipers or semiautomatic edge detection software must be utilized for CIMT.
  - 6.2.4B Equipment Quality Control
    - 6.2.4.1B Equipment used for testing must be maintained in good operating condition.
    - 6.2.4.2B Equipment maintenance must include, but is not limited to:

- 6.2.4.3B recording of the method and frequency of maintenance of all imaging equipment and non-imaging equipment;
- 6.2.4.4B establishment of and adherence to a policy regarding routine safety inspections and testing of all facility electrical equipment;
- 6.2.4.5B 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.

## **STANDARD – Protocols**

- 6.3B Each screening examination performed must have a written protocol. The protocol must include:
  - 6.3.1B equipment to be used for each examination;
  - 6.3.2B the elements of proper technique (also see [STANDARD – Techniques](#));
  - 6.3.3B the anatomic extent that constitutes a screening examination;
    - 6.3.3.1B Bilateral testing is considered a complete screening examination.
  - 6.3.4B 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](#));
  - 6.3.5B a description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used to supplement grayscale imaging, spectral Doppler and velocity measurements;
- 6.4B Vascular screening examinations must be interpreted and reported by the Medical Director or a member of the medical staff of the screening service.

## **STANDARD – Techniques**

- 6.5B Appropriate techniques must be used for screening exams to assess the presence or absence of any abnormalities.
  - 6.5.1B Elements of proper technique include, but are not limited to:
    - 6.5.1.1B performance of an examination according to the facility specific, written protocol;
    - 6.5.1.2B proper patient positioning;
    - 6.5.1.3B patient preparation;
    - 6.5.1.4B appropriate equipment and transducer selection;
    - 6.5.1.5B appropriate transducer positioning;
    - 6.5.1.6B proper sample volume size and positioning;
    - 6.5.1.7B optimization of equipment gain and display settings;
    - 6.5.1.8B a spectral Doppler angle of 60 degrees or less with respect to the vessel wall and/or direction of blood flow when measuring velocities;
    - 6.5.1.9B proper measurement of spectral velocities as required by the protocol;

- 6.5.1.10B identification of vessels by imaging and Doppler;
- 6.5.1.11B use of computerized assisted electronic calipers or semiautomatic edge detection software for CIMT measurements;
- 6.5.1.12B ankle brachial index (ABI):
  - i. 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;
  - ii. 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**

- 6.6B Each screening examination must provide sufficient documentation to allow proper interpretation including, but not limited to:
  - 6.6.1B grayscale images;
  - 6.6.2B Doppler waveforms;
  - 6.6.3B velocity measurements;
  - 6.6.4B other measurements or images as required by the screening protocol.
- 6.7B Vascular screening examinations are interpreted and reported by the Medical Director or a member of the medical staff of the screening service.
- 6.8B A final screening report or document that describes the results of the examination findings and recommended follow-up must be provided to the participant and/or participant’s physicians.
- 6.9B Extracranial Cerebrovascular Screening
  - 6.9.1B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:
    - 6.9.1.1B Normal Examination:
      - i. One site in the proximal internal carotid artery with peak systolic and end diastolic velocity measurements.
    - 6.9.1.2B Abnormal Examination:
      - i. Peak systolic and end diastolic velocity measurements documenting area(s) of significant findings in accordance with the screening diagnostic criteria.
- 6.10B Carotid Intima-Media Thickness (CIMT) Screening

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 IAC does not advocate use of carotid IMT as a screening method for atherosclerotic risk until further peer-reviewed literature evolves. If providers choose to perform CIMT testing, rigorous methodological protocols should be strictly followed.

6.10.1B Long axis grayscale images must be documented as required by the protocol and must include at a minimum:

6.10.1.1B measurements obtained during end diastole from at least three longitudinal imaging planes (optimal and two complementary imaging planes – anterior, lateral or posterior to the optimal angle);

6.10.1.2B measurements 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.

6.10.1.3B when plaque is present, characterization and/or dimensions.

#### 6.11B Peripheral Arterial Screening

6.11.1B Ankle brachial index (ABI):

6.11.1.1B bilateral brachial artery systolic pressures;

6.11.1.2B bilateral ankle systolic pressures from the distal posterior tibial (PT) artery and distal anterior tibial (AT)/dorsalis pedis (DP) artery.

#### 6.12B Abdominal Aorta Aneurysm Screening

6.12.1B Grayscale images must be documented as required by the protocol and must include at a minimum:

6.12.1.1B Normal Examination:

- i. One transverse image (defined as perpendicular to the long axis of the aorta) with the single widest outer wall to outer wall diameter measurement.

6.12.1.2B Abnormal Examination:

- i. One Transverse image (defined as perpendicular to the long axis of the aorta) with the single widest outer wall to outer wall diameter measurement.
- ii. One Transverse image (defined as perpendicular to the long axis of the aorta) with the single widest outer wall to outer wall diameter measurement of a non-dilated segment for comparison.

### **STANDARD – Procedure Volumes**

6.13B Records must be maintained that permit evaluation of annual procedure volumes. These records must include information on:

6.13.1B indication for the examination;

6.13.2B examination(s) performed;

6.13.3B findings.

*(See Guidelines on Page 59 for further recommendations.)*

## Section 6B: Screening Testing *Guidelines*

- 6.13B *The annual procedure volume should be sufficient to maintain proficiency in exam techniques and interpretation.*
- *In general, a facility should perform a minimum of 50 (25 for CIMT) screening examinations per testing section annually.*

# Part C:

## Quality Improvement

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### Section 1C: Quality Improvement Program

#### STANDARD – QI Program

1.1C Quality Improvement (QI) must be performed.

1.1.1C There must be a written policy regarding QI for all procedures performed in the facility.

#### STANDARD – QI Documentation

1.2C A correlation log for each area of testing must demonstrate greater than 70% accuracy agreement.

1.3C 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 facility is unable to obtain the minimum number of correlations, alternative methods for QI may be considered on an individual facility basis. The facility must submit the written plan of action for documentation of ongoing quality measures to assess the accuracy of examinations.

# Section 2C: Quality Improvement Measures

## STANDARD – QI Measures

2.1C All testing correlation must demonstrate greater than 70% accuracy agreement.

Comment: Correlation with operative findings is strongly discouraged.

### 2.1.1C Extracranial Cerebrovascular QI Program

2.1.1.1C Results of extracranial cerebrovascular exams must be regularly correlated with other imaging modalities, preferably angiographic and/or surgical findings as described below.

- i. The facility 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.
- ii. 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 facility.
- iii. For extracranial cerebrovascular testing, a minimum of 30 internal carotid arteries must be correlated.

*(See Guidelines on Page 63 for further recommendations.)*

### 2.1.2C Intracranial Cerebrovascular QI Program

2.1.2.1C Results of intracranial cerebrovascular examinations must be regularly correlated with other imaging modalities, preferably angiographic and/or surgical findings as described below.

- i. The facility must have a written procedure for regular correlation of the intracranial cerebrovascular exams 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.).
- ii. 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 facility.
- iii. 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.

*(See Guidelines on Page 63 for further recommendations.)*

### 2.1.3C Peripheral Arterial QI Program

2.1.3.1C Results of peripheral arterial examinations must be regularly correlated with other imaging modalities, preferably angiographic and/or surgical findings as described below.

- i. The facility 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.

- ii. 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 facility.
- iii. A minimum of 30 extremities must be correlated

*(See Guidelines on Page 63 for further recommendations.)*

#### 2.1.4C Peripheral Venous QI Program

##### 2.1.4.1C Results of peripheral venous examinations must be regularly correlated.

- i. The facility must have a written procedure for regular correlation of venous examinations with one or more of the following methods:
  - repeat examination performed within three days of the initial examination;
  - clinical outcome;
  - case peer review by a second interpreting physician that includes comments regarding: technical adequacy, interpretation accuracy and final report completeness;
  - comparison with venography or surgical pathology.
- ii. 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 facility.
- iii. A minimum of 30 extremities must be correlated.

#### 2.1.5C Visceral Vascular QI Program

##### 2.1.5.1C Results of visceral vascular examinations must be regularly correlated with other imaging modalities, preferably angiographic and/or surgical findings as described below.

- i. The facility 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.
- ii. The correlation must be reported using the comparison of the results of the visceral vascular exam 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 facility.
- iii. A minimum of 15 patient examinations must be correlated

*(See Guidelines on Page 63 for further recommendations.)*

#### 2.1.6C Screening QI Program

##### 2.1.6.1C 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.

- i. The facility must have a written procedure for regular correlation of the vascular screening examinations with complete diagnostic examination, angiographic findings produced by digital subtraction angiography, contrast enhanced computed tomography, magnetic resonance angiography or operative findings.
- ii. For CIMT – acceptable methods for mandatory correlation include repeat examination or over-reading including recalculation of the CIMT.

- iii. 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 facility.
- iv. A minimum of 15 screening examination per each type of screening performed must be correlated.

*(See Guidelines below for further recommendations.)*

## **Section 2C: Quality Improvement Measures**

### ***Guidelines***

*2.1.1.1C, 2.1.2.1C, 2.1.3.1C, 2.1.5.1C, 2.1.6.1C - Comment: The time interval between the vascular testing facility examination and the correlative study for quality improvement purposes should be appropriate for the disease being correlated. For diseases which may change rapidly (e.g., vasospasm, venous disease), 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 testing facility examination and the correlative study, comparison of these studies is not an acceptable quality improvement mechanism.*

## Section 3C: Quality Improvement Meetings

### STANDARD – QI Meetings

- 3.1C A minimum of two vascular testing facility QI meetings per year must be held to:
  - 3.1.1C review the results of comparative studies;
  - 3.1.2C address discrepancies;
  - 3.1.3C discuss difficult cases;
  - 3.1.4C address facility QI issues.
- 3.2C Minutes of the QI meetings must be maintained.
- 3.3C Participation by the Medical and Technical Directors (or their designee) is required.
- 3.4C Medical and technical staff must participate in one of two meetings and participation must be documented.

# References

1. Burke GL, Evans GW, Riley WA, Sharrett AR, Howard G, Barnes RW, Rosamond W, Crow RS, Rautaharju PM, Heiss G. Arterial wall thickness is associated with prevalent cardiovascular disease in middle-aged adults: the Atherosclerosis Risk in Communities (ARIC) Study. *Stroke* 1995; 26:386-391. <http://stroke.ahajournals.org/cgi/content/full/26/3/386>
2. O'Leary DH, Polak JF, Wolfson SKJr, Bond MG, Bommer W, Sheth S, Psaty Bm, Sharrett AR, Manolio TA. Use of Sonography to evaluate carotid atherosclerosis in the elderly: the Cardiovascular Health Study. *Stroke* 1991; 22:1155-1163. <http://stroke.ahajournals.org/cgi/content/abstract/22/9/1155>
3. Stensland-Bugge E, Bonna KH, Joakimsen O. Reproducibility of ultrasonographically determined intima-media thickness is dependent on arterial wall thickness: the Tromso Study. *Stroke* 1997; 28:1972-1980. <http://stroke.ahajournals.org/cgi/content/full/28/10/1972?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=lumen&searchid=1&FIRSTINDEX=40&resourcetype=HWFID>
4. Crouse JR III, Craven TE, Hagaman AP, Bond MG. Association of coronary disease with segment-specific intimal-medial thickening of the extracranial carotid artery. *Circulation* 1995; 92:1141-1147. [www.circ.ahajournals.org/cgi/content/full/92/5/1141](http://www.circ.ahajournals.org/cgi/content/full/92/5/1141)
5. Stein JH, Korcarz CE, Hurst RT, et al. American Society of Echocardiography Carotid Intima Media Thickness Task Force. Use of carotid ultrasound to identify subclinical vascular disease and evaluate subclinical cardiovascular disease risk: a consensus statement from the American Society of Echocardiography Intima Media Thickness Task Force. *J Am Soc Echo* 2008; 21:93-111. [www.asefiles.org/UseofCarotidUltrasound.pdf](http://www.asefiles.org/UseofCarotidUltrasound.pdf)
6. Wendelhag I, Liang Q, Gustavsson T, Wikstrand J. A new automated computerized analyzing system simplifies readings and reduces the variability in ultrasound measurement of intima-media thickness. *Stroke* 1997; 28:2195-2200. <http://stroke.ahajournals.org/cgi/content/abstract/28/11/2195>
7. Devereux RB, Waeber B, Roman MJ. Conclusions on the measurement of arterial wall thickness: anatomic, physiologic and methodologic considerations. *J Hypertens* 1992; 10(suppl 6):S119-S121. [http://journals.lww.com/jhypertension/Abstract/1992/08001/Conclusions\\_on\\_the\\_measurement\\_of\\_arterial\\_wall.30.aspx](http://journals.lww.com/jhypertension/Abstract/1992/08001/Conclusions_on_the_measurement_of_arterial_wall.30.aspx)
8. Ebrahim S, Papacosta O, Whincup P, Wannamethee G, Walker M, Nicolaides AN, Dhanjil S, Griffin M, Belcaro G, Rumley A, Lowe GDO. Carotid plaque, intima media thickness, cardiovascular risk factors, and prevalent cardiovascular disease in men and women: The British Regional Heart Study. *Stroke* 1999; 30:841-850. <http://stroke.ahajournals.org/cgi/content/full/30/4/841>
9. D'Agostino RB Jr, Burke G, O'Leary D, Rewers M, Selby J, Savage PJ, Saad MF, Bergman RN, Howard G, Wagenknecht L, Haffner SM. Ethnic differences in carotid wall thickness: the Insulin Resistance Atherosclerosis Study. *Stroke* 1996; 27:1744-1749. <http://stroke.ahajournals.org/cgi/content/full/27/10/1744>
10. Roman, MJ, Pini R, Pickering TG, Devereux RB. Noninvasive measurements of arterial compliance in hypertensive compared with normotensive adults. *J Hypertens* 1992; 10(suppl6):S115-S118. [http://journals.lww.com/jhypertension/Abstract/1992/08001/Non\\_invasive\\_measurements\\_of\\_arterial\\_compliance.29.aspx](http://journals.lww.com/jhypertension/Abstract/1992/08001/Non_invasive_measurements_of_arterial_compliance.29.aspx)
11. Joakimsen O, Bonna KH, Stensland-Bugge E. Reproducibility of ultrasound assessment of carotid plaque occurrence, thickness and morphology: the Tromso Study. *Stroke* 1997; 28:2201-2207. <http://stroke.ahajournals.org/cgi/content/full/28/11/2201>
12. Touboul PJ, Hennerici MG, Meairs S, et al. Mannheim carotid intima-media thickness consensus (2004-2006). An update on behalf of the Advisory Board of the 3<sup>rd</sup> and 4<sup>th</sup> Watching the Risk Symposium, 13<sup>th</sup> and 15<sup>th</sup> European Stroke Conferences, Mannheim, Germany, 2004, and Brussels, Belgium, 2006. *Cerebrovasc Dis* 2007; 23:75-80. [www.online.karger.com/ProdukteDB/produkte.asp?Aktion=ShowFulltext&ArtikelNr=97034&Ausgabe=232229&ProduktNr=224153](http://www.online.karger.com/ProdukteDB/produkte.asp?Aktion=ShowFulltext&ArtikelNr=97034&Ausgabe=232229&ProduktNr=224153)
13. Riley, WA. Cardiovascular Risk Assessment in individual patients from carotid intimal-medial thickness measurements. *Current Atherosclerosis Reports* 2004, 6:225-231. [www.current-reports.com/article\\_frame.cfm?PubID=AT06-3-2-03&Type=Abstract&Keywords=Cardiovascular%20risk%20assessment%20in%20individual&HitNum=1](http://www.current-reports.com/article_frame.cfm?PubID=AT06-3-2-03&Type=Abstract&Keywords=Cardiovascular%20risk%20assessment%20in%20individual&HitNum=1)