

# 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*.

New or emerging technologies, protocols and other novel imaging or interventional approaches not included in guidelines published by professional societies must have supporting documentation that demonstrates adherence to manufacturer's training, safety specifications and quality control specifications as applicable.

Facilities are encouraged to <u>contact the IAC</u> for guidance related to utilization of new technology not currently addressed in the IAC *Standards*.

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

Standards that are highlighted are content changes that were made as part of the February 15, 2024 revision. These Standards become effective on August 15, 2024. Facilities applying for accreditation after August 15, 2024 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

## **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 <u>Medical Director Required Training and Experience</u>

At the time of initial application for accreditation or at the time of appointment as Medical Director, he/she must demonstrate an appropriate level of training and experience by meeting one or more of the following:

- 1.1.1.1A Physician Credential for Vascular Interpretation
  - i. Registered Physician in Vascular Interpretation (RPVI)
  - ii. Registered Physician in Neurovascular Interpretation (RPNI)

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

- 1.1.1.2A 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 100 cases
- 1.1.1.3A 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 test.
- iii. Experience must be documented with a letter from the Medical Director of the facility where the experience was obtained.
- iv. 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 100 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.

- 1.1.1.4A 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 300 cases

#### 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 participate in regular Quality Improvement (QI) meetings, case study review conferences, personnel interviews and other facility operations. This may be accomplished through tele/video conferencing.

#### 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.
  - i. A minimum of 15 hours of Category 1 CME is required every three years.
  - ii. At least one hour of the 15 CME must be relative to work-related musculoskeletal disorders (WRMSD).
  - iii. 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 RPNI certification.

(See Guidelines on Page 13-14 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 <u>Technical Director Required Training and Experience</u>

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. Neurovascular Specialist (NVS) (extracranial and intracranial testing only);
  - vi. Registered Phlebology Sonographer (RPhS) (peripheral venous testing only);
  - vii. Canadian Registered Vascular Sonographer (CRVS) (for technologists practicing in Canada only).
- 1.2.1.2A At the time of initial accreditation or at the time of appointment to the Technical Director position, he/she must demonstrate an appropriate level of training and experience by having performed the following minimum number of studies for each testing area applied for:
  - 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 100 cases

#### 1.2.2A <u>Technical Director Responsibilities</u>

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.
  - i. A minimum of 15 hours of CME is required every three years.
  - ii. At least one hour of the 15 CME must be relative to work-related musculoskeletal disorders (WRMSD).
  - iii. The CME requirement will be waived if:
    - acquired an appropriate vascular credential within the previous threeyear period.

(See Guidelines on Page 13-14 for further recommendations)

#### STANDARD - Medical Staff

- 1.3A A qualified medical staff may 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 <u>Medical Staff Required Training and Experience</u>

At the time of initial application for accreditation or at the time of appointment to the medical staff, he/she must demonstrate an appropriate level of training and experience by meeting at least one of the following:

- 1.3.1.1A Physician Credential for Vascular Interpretation
  - i. Registered Physician in Vascular Interpretation (RPVI)

ii. Registered Physician in Neurovascular Interpretation (RPNI)

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

- 1.3.1.2A 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 100 cases
- 1.3.1.3A 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.
  - iii. Experience must be documented with a letter from the Medical Director of the facility where the experience was obtained.
  - iv. 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 100 cases

(See Guidelines on Page 13-14 for further recommendations)

- 1.3.1.4A 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 300 cases

#### 1.3.2A <u>Medical Staff Responsibilities</u>

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.
  - i. A minimum of 15 hours of Category 1 CME is required every three years.
  - 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 RPNI certification.

(See Guidelines on Page 13-14 for further recommendations)

#### STANDARD - Technical Staff

- 1.4A A qualified technical staff may be designated for the facility.
  - 1.4.1A Technical Staff Required Training and Experience
    - 1.4.1.1A At the time of initial application or at the time of appointment to the technical staff position, he/she must demonstrate an appropriate level of training and experience by having performed the following minimum number of studies for each testing area applied for:
      - 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 – 100 cases

(See Guidelines on Page 13-14 for further recommendations)

- 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:
    - Registered Vascular Technologist (RVT);
    - Registered Vascular Specialist (RVS);
    - Registered Technologist Vascular Sonography [RT(VS)];
    - Registered Diagnostic Medical Sonographer in Abdomen [RDMS (AB)] (visceral vascular testing only);
    - Neurovascular Specialist (NVS) (extracranial and intracranial testing only);
    - Registered Phlebology Sonographer (RPhS) (peripheral venous testing only);
    - Canadian Registered Vascular Sonographer (CRVS) (for technologists practicing in Canada only).
  - ii. Provisional Staff
    - Individuals employed in an accredited facility who are not certified by a credentialing organization must be listed in the application as provisional technical staff. These individuals must only work under direct supervision of a credentialed vascular sonographer and must obtain an appropriate vascular testing credential within two years from the start date of training.

#### 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.
  - 1.4.3.2A A minimum of 15 hours of CME is required every three years.
  - 1.4.3.3A At least one hour of the 15 CME must be relative to work-related musculoskeletal disorders (WRMSD).
  - 1.4.3.4A The CME requirement will be waived if:
    - i. the technologist has acquired an appropriate vascular credential within the previous three-year period.

(See Guidelines on Page 13-14 for further recommendations)

#### **STANDARD – Support Services**

- 1.5A Ancillary personnel (clerical, nursing, transport, etc.) necessary for safe and efficient patient care must be provided.
  - 1.5.1A The Medical Director must ensure that support services are appropriate and in the best interest of patient care and safety.
  - 1.5.2A Clerical and administrative support must be sufficient to ensure efficient facility operational record keeping.
  - 1.5.3A Nursing and ancillary services must be sufficient to ensure quality patient care and safety.

### Section 1A: Personnel and Supervision Guidelines

#### 1.1A <u>Medical Director – Continuing Experience</u>

- The monthly volume should be sufficient to maintain proficiency in examination 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.

#### 1.1.3A <u>Medical Director – Continuing Medical Education</u>

- To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.
- Facility internal Quality Improvement (QI) meetings are not eligible as part of this CME requirement.

#### 1.2A <u>Technical Director – Continuing Experience</u>

- The monthly volume should be sufficient to maintain proficiency in examination 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 <u>Technical Director – Continuing Medical Education</u>

- To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing examinations.
- Facility internal Quality Improvement (QI) meetings are not eligible as part of this CME requirement.

#### 1.3A <u>Medical Staff – Continuing Experience</u>

- 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.

#### 1.3.1.3A <u>Medical Staff Required Training and Experience</u>

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.

#### 1.3.3A Medical Staff Continuing Medical Education

- To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.
- Facility internal Quality Improvement (QI) meetings are not eligible as part of this CME requirement.

#### 1.4A <u>Technical Staff – Continuing Experience</u>

- The monthly volume should be sufficient to maintain proficiency in examination 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.

#### 1.4.1.1A <u>Technical Staff – Required Training & Experience</u>

An individual who does not meet the testing volume requirements for any testing section must be supervised by the Technical Director until the required volumes are achieved.

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).

#### 1.4.3A <u>Technical Staff Continuing Medical Education</u>

- To be relevant the course content must address principles, instrumentation, techniques or interpretation of noninvasive vascular testing.
- Facility internal Quality Improvement (QI) meetings are not eligible as part of this CME requirement.

## **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.
  - 2.2.1A Remote interpretation of examinations must be performed in an environment that ensures appropriate safeguards to protect the privacy of patient health information.

#### STANDARD - Storage

2.3A Reports and exam records must be stored on media appropriate for long term retention and review.

## 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.

(See Guidelines on Page 22 for further recommendations.)

- 3.1.2A A complete, accurate and signed final report must be generated as outlined in <u>STANDARD</u>: <u>Examination Interpretation and Reports</u>, 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 for arterial duplex examinations and venous examinations as
	required by the venous protocol;

- 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 22 for further recommendations.)

- 3.2.7A The verified signed final report must be available within two business days of the examination.
- 3.2.8A The name 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.

  Communication of preliminary findings must be documented in the patient's medical record.
  - 3.2.9.1A A policy for communicating a substantially different final interpretation from the preliminary findings must be defined.
- 3.2.10A A policy for communication of urgent findings, immediately following the examination, must be defined and must include documentation in the medical record of date, time and name of the physician/nurse who was notified of the findings.

#### 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 <u>STANDARD – Examination Interpretation and Reports</u>.

#### 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 Other diagnostic criteria must be based on published reports or internally generated and validated as outlined in <a href="Part C: Quality Improvement">Part C: Quality Improvement</a>.
    - 3.4.1.1A Internally validated diagnostic criteria must have retrievable records supporting the validation process.

#### 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;
  - 3.5.1.5A stent(s) (when present).
- 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, including ICA/CCA peak-systolic velocity ratio, spectral Doppler waveform analysis and imaging are used to document the severity, location, extent and whenever possible etiology.

Comment: IAC strongly recommends use of the <u>IAC-modification to the SRU</u> Consensus Criteria for Interpretation of Internal Carotid Artery Stenosis.

- 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 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);
  - 3.7.1.5A stent(s) (when present);
  - 3.7.1.6A bypass grafts (when present);
  - 3.7.1.7A dialysis access (when present);
  - 3.7.1.8A abdominal agrta examination for aneurysm and/or stenosis (when present);
  - 3.7.1.9A aortic endograft (when present).
- 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 toe brachial index (TBI) (if performed);
  - 3.7.2.3A segmental limb pressures (if used);
  - 3.7.2.4A continuous wave or pulsed wave Doppler waveforms;
  - 3.7.2.5A air plethysmographic waveforms (PVR);
  - 3.7.2.6A photoplethysmography signal amplitude and waveform;
  - 3.7.2.7A treadmill exercise/stress testing.

#### 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 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 vein patency;
- 3.8.2.3A vein size (for mapping or reflux testing);
- 3.8.2.4A venous reflux in seconds/time;
- 3.8.2.5A arteriovenous fistula (AVF) or dialysis access grafts;
- 3.8.2.6A stent(s) (when present).

#### 3.9A <u>Visceral Vascular</u>

- 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 (as required by the protocol);
  - 3.9.1.5A color Doppler images (if used);
  - 3.9.1.6A stent(s) (when present);
  - 3.9.1.7A abdominal agrta examination for aneurysm and/or stenosis (when present);
  - 3.9.1.8A aortic endografts (when present).

#### 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);
  - 3.10.1.5A ankle/brachial index.
- 3.10.2A Each screening examination must have specific reporting criteria.
  - 3.10.2.1A Extracranial cerebrovascular screening:

Internal Carotid Artery (ICA) Stenosis/Disease – These criteria must state how velocity measurements, including ICA/CCA peak-systolic velocity ratio, spectral Doppler waveform analysis and imaging are used to document the severity, location, extent and whenever possible etiology.

## Comment: IAC strongly recommends use of the <u>IAC-modification to the SRU</u> Consensus Criteria for Interpretation of Internal Carotid Artery Stenosis.

- 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):

- 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. atherosclerotic changes and/or thrombus (when identified);
- iv. aneurysmal status not defined due to non-visualization.

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

- 3.1.1A Final submission of representative case studies to the IAC must be in a digital format (e.g., CD, DVD or flash drive).
- 3.2.6*A* 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/

www.sdms.org/OSHA/etool.asp

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 <u>intersocietal.org/helpful-resources/sample-documents-repository</u>.

## 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 a lead technologist is appointed at each multi-site facility and reports to the Technical Director weekly, either in person or via tele/video conferencing to ensure compliance with the *IAC Vascular Testing Standards*.
      - i. Documentation of supervision policy must be available upon request.
      - ii. The lead technologist must:
        - supervise and assist other technical staff members in performing examinations;
        - oversee the daily activities of the multi-site.
  - 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.
    - 6.1.6.1A All staff must participate in at least one QI meeting per year (Refer to Part C: Quality Improvement).
  - 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/legal/policies-procedures.

## **Part B: Examinations and Procedures**

## **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 30 for further recommendations.)

#### **STANDARD** – **Equipment**

- 1.2B Equipment must provide accurate data.
  - 1.2.1B <u>Imaging Equipment</u> 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 30 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 <u>STANDARD Techniques</u>);
- 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 <u>STANDARD Documentation</u>);
- 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 30 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.

Internal Carotid Artery (ICA) Stenosis/Disease – These criteria must state how velocity measurements, ICA/CCA peak-systolic velocity ratio, spectral Doppler waveform analysis and imaging are used to document the severity, location, extent and whenever possible etiology.

Comment: IAC strongly recommends use of the <u>IAC-modification to the SRU Consensus Criteria for Interpretation of Internal Carotid Artery Stenosis</u>.

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;
  - 1.7.1.4B carotid artery stent (if present) including proximal and distal ends.
- 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;
  - 1.7.2.7B carotid artery stent (if present).
    - i. native artery at the proximal end of the stent;
    - ii. proximal stent;
    - iii. mid stent;

- iv. distal stent;
- v. native artery at the distal end of the stent.

Comment: Limitations of the study must be documented in the final report.

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 on Page 30 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 maintenance 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 35 for further recommendations.)

#### STANDARD - Equipment

- 2.2B Equipment must provide accurate data.
  - 2.2.1B <u>Imaging Equipment</u> 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;
    - a visual display, an audible output, and a permanent recording of the Doppler waveform and corresponding image which includes the Doppler angle (when appropriate).
  - 2.2.2B Pulsed wave (PW) Doppler, if used for testing, must be provided with:
    - 2.2.2.1B Doppler transducer frequencies appropriate for the vessels evaluated;
    - 2.2.2.2B Doppler waveform display demonstrating bidirectional flow and signal intensity;
    - 2.2.2.3B an audible output and a permanent recording of the waveform.
  - 2.2.3B Equipment Quality Control
    - 2.2.3.1B Equipment used for diagnostic testing must be maintained in good operating condition.
    - 2.2.3.2B Equipment maintenance must include, but is not limited to:
      - i. record of the method and frequency of maintenance of all intracranial testing equipment;
      - ii. establishment of and adherence to a policy regarding routine safety inspections and testing of all facility electrical equipment.

(See Guidelines on Page 35 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 <u>STANDARD – Techniques</u> );			
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:			
2.3.5B	anterior and posterior circulations including flow detection via temporal, orbital and suboccipital acoustic window (when appropriate);			
	2.3.5.1B	submandibular (when appropriate) windows must be described;		
	2.3.5.2B	variations in technique following vascular intervention;		
	2.3.5.3B	variations in technique and documentation for limited examinations.		
2.3.6B	separate written protocols for additional intracranial cerebrovascular examinations (if performed) must include, but may not be limited to:			
	2.3.6.1B	emboli detection;		
	2.3.6.2B	vasomotor reactivity;		
	2.3.6.3B	right-to-left shunt;		
	2.3.6.4B	assessment of cerebral circulatory arrest;		
	2.3.6.5B	peri-procedural or intra-operative monitoring;		
	2.3.6.6B	monitoring of reperfusion therapies in acute stroke;		
	2.3.6.7B	monitoring in the neuro-intensive care setting.		
2.3.7B	documentation that must be acquired for normal exams and the additional documentation that must be acquired to describe abnormalities, if present (also see <u>STANDARD – Documentation</u>			
2.3.8B	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;			
2.3.9B	depth ranges for each vessel segment in adults and children (when appropriate);			
2.3.10B	extent of power reduction to be used for transorbital examinations.			
	2.3.10.1B	For patient safety, the output power must not exceed 10% of maximum emitted power or 17 mW per cm2 or equivalent measurements.		

(See Guidelines on Page 35 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 Doppler and by imaging (when appropriate).

(See Guidelines on Page 35 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 proximal, at the site of stenosis and distal to the stenosis and/or obstruction (when possible).

#### 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 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 35 for further recommendations.)

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

- 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
  - 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.
- 2.2.3.2B The maintenance 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 45 for further recommendations.)

#### STANDARD - Equipment

- 3.2B Equipment must provide accurate data.
  - 3.2.1B <u>Imaging Equipment</u> 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 <u>Supplemental Equipment</u>
    - 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 required by the 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 45 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);
  - 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); a description of how color Doppler or other flow imaging modes (e.g., power Doppler) are used 3.3.8B to supplement grayscale imaging, spectral Doppler and velocity measurements: ultrasound contrast material may be utilized for examination of the visceral vessels and aortic 3.3.9B endografts. Standard protocols regarding ultrasound contrast examination and off-label use must be described.

(See Guidelines on Page 45 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 Stent(s) when present, including proximal and distal ends.
- 3.7.1.3B 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;
  - viii. stent(s) when present.
    - native artery at the proximal end of the stent;
    - proximal stent;
    - mid stent;
    - distal stent;
    - native artery at the distal end of the stent.
- 3.7.1.4B 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;
    - vi. stent(s) when present, including proximal and distal ends.
  - 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;
    - vii. stent(s) when present must include:
      - native artery at the proximal end of the stent;

- proximal stent;
- mid stent;
- distal stent;
- native artery at the distal end of the stent.
- 3.7.2.3B Abnormalities require additional images, waveforms and velocity measurements.

Comment: Long stents (e.g., femoral-to-popliteal covered stent graft) may require multiple mid stent images to localize stenosis when present.

Comment: Limitation of the study must be documented in the report.

- 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).
  - 3.8.3B Photoplethysmography (if performed) must be documented as required by the protocol and must include at a minimum:
    - 3.8.3.1B documentation of the digital waveforms.
  - 3.8.4B Treadmill exercise/stress testing, if performed, must be documented as required by the protocol and must include at a minimum:
    - 3.8.4.1B pressures obtained at rest;
    - 3.8.4.2B pressures obtained at timed intervals immediately after exercise;
    - 3.8.4.3B for treadmill-based protocols, the time of onset of claudication and maximal walking time.
- 3.9B Abdominal aorta examinations (if performed) must be documented as required by the protocol and must include at a minimum:
  - 3.9.1B 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:

- 3.9.1.1B proximal aorta;
- 3.9.1.2B mid aorta;
- 3.9.1.3B distal aorta;
- 3.9.1.4B common iliac arteries at the bifurcation.
- 3.9.2B Long axis grayscale images must be documented as required by the protocol and must include at a minimum:
  - 3.9.2.1B proximal aorta;
  - 3.9.2.2B mid aorta;
  - 3.9.2.3B distal aorta;
  - 3.9.2.4B documentation of aneurysms (if present) must include the widest size of the aorta measured outer wall to outer wall;
  - 3.9.2.5B additional images proximal and distal to the aneurysm.
- 3.9.3B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:
  - 3.9.3.1B aorta at/or proximal to the renal artery origins;
  - 3.9.3.2B mid aorta;
  - 3.9.3.3B distal aorta:
  - 3.9.3.4B right common iliac artery;
  - 3.9.3.5B left common iliac artery.

- 3.9.4B Abnormalities require additional images, waveforms and velocity measurements.
- 3.10B Arteriovenous fistula (AVF)/dialysis access grafts, if performed, must be documented as required by the protocol and must include at a minimum:
  - 3.10.1B A description of the type of fistula or graft.
  - 3.10.2B Long axis grayscale and/or color Doppler images must be documented as required by the protocol and must include at a minimum:
    - 3.10.2.1B inflow artery proximal to graft or fistula;
    - 3.10.2.2B anastomotic site(s);
    - 3.10.2.3B outflow vein;
    - 3.10.2.4B axillary and subclavian veins (when appropriate).
  - 3.10.3B Spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:

- 3.10.3.1B inflow artery;
  - i. proximal and distal anastomoses (graft);
  - ii. anastomosis site (fistula);
  - iii. outflow vein beyond anastomosis.
- 3.10.3.2B Blood flow volume must be documented from at least one site.
- 3.10.3.3B 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.

- 3.10.4B Abnormalities require additional images, waveforms and velocity measurements.
- 3.11B Abdominal aortic aneurysm following endovascular aneurysm repair (EVAR).
  - 3.11.1B Transverse view (defined as perpendicular to the long axis of the aorta, including endograft) 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:
    - 3.11.1.1B proximal aorta;
    - 3.11.1.2B mid aorta;
    - 3.11.1.3B distal aorta;
    - 3.11.1.4B common iliac arteries at the bifurcation;
    - 3.11.1.5B position of endograft.
  - 3.11.2B Long axis grayscale images must be documented as required by the protocol and must include at a minimum:
    - 3.11.2.1B proximal aorta;
    - 3.11.2.2B mid aorta;
    - 3.11.2.3B distal aorta;
    - 3.11.2.4B documentation of aortic aneurysm 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;
    - 3.11.2.5B location of endograft including proximal and distal attachment sites and limb components.
  - 3.11.3B Color Doppler images and spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:
    - 3.11.3.1B aorta proximal to the endograft;
    - 3.11.3.2B proximal endograft;
    - 3.11.3.3B distal endograft;

- 3.11.3.4B iliac limbs of the endograft;
- 3.11.3.5B outflow vessels distal to the endograft;
- 3.11.3.6B the aneurysm sac outside of the endograft, including documentation of blood flow (endoleak) if identified;
- 3.11.3.7B location and patency of branch vessels at the site(s) of intervention.
- 3.11.4B Images following the administration of ultrasound contrast agents (if used) must be obtained in locations of identified or potential endoleaks.
- 3.11.5B The location of the proximal and distal points of graft attachment and type of endoleak (if identified) must be included in the final report. Results of secondary interventions, (placement of additional stent[s], embolization of endoleaks, etc.) must be included in reports of subsequent examination.

Comment: The facility can include abdominal aorta and EVAR 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 and EVAR examinations can be included in the visceral vascular testing section.

#### STANDARD - Procedure Volumes

- 3.12B Records must be maintained that permit evaluation of annual procedure volumes. These records must include:
  - 3.12.1B indication for the examination;
  - 3.12.2B technologist performing the examination;
  - 3.12.3B examination(s) performed;
  - 3.12.4B examination findings;
  - 3.12.5B physician interpreting the examination.

# 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 maintenance 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.
3.9.3B	Color Doppler images may supplement grayscale imaging but does not substitute for it.
3.12B	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 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 53 for further recommendations.)

#### STANDARD - Equipment

- 4.2B Equipment must provide accurate data.
  - 4.2.1B <u>Imaging Equipment</u> 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;
      - 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 53 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 53 for further recommendations.)

#### STANDARD - Techniques

- 4.4B Appropriate techniques must be used for the evaluation of the peripheral venous deep and superficial systems, stents, hemodialysis access arteriovenous fistulae (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;
      - When the primary assessment is for valvular function, the limb must be placed in a dependent position. Standing is the preferred position if not constrained by the patient's physical condition. Sitting or reverse Trendelenburg may be used if the patient cannot stand. Patient position must be noted in the final report.
    - 4.4.1.3B patient preparation;
    - 4.4.1.4B appropriate equipment and transducer selection;
    - 4.4.1.5B appropriate transducer positioning and orientation;
    - 4.4.1.6B proper Doppler 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 in the dependent position;
        - be acquired in transverse, anterior wall to posterior wall, consistently, or as required by the protocol;
        - As required by the protocol for active or healed venous ulcers, perforator vein diameter measurements must be acquired where the perforator traverses the deep fascia;
        - assure that no external pressure is applied to the vein.

- 4.4.1.9B identification of vessels by imaging and Doppler using appropriate terminology for vessel nomenclature and anatomic level;
- 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;
- 4.4.1.12B Manual distal compression or automated rapid cuff inflation/deflation devices must be used as provocative maneuvers assessing valvular function, to determine competency or reflux in all lower extremity venous segments evaluated.
  - i. Valsalva maneuvers may be substituted for distal compression when examining the common femoral vein and the saphenofemoral junction.

#### 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 spectral waveforms with reflux duration time documented;
    - 4.5.3.1B Venous flow must be documented below the baseline prior to augmentation to validate flow reversal above the baseline.
  - 4.5.4B other images and waveforms as required by the protocol;
  - 4.5.5B 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.
  - 4.6.2B Superficial reflux must be traced to its source (e.g., saphenous junctions, great, small, anterior accessory saphenous vein, perforating vein, pelvic origin varicose veins). Whenever possible and documented with additional images as indicated; with reflux duration time documented.
- 4.7B Peripheral Venous Documentation
  - 4.7.1B <u>Lower Extremity Venous Duplex for Thrombosis and Patency</u>
    - 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 including the gastrocnemius veins, soleal veins and superficial veins when clinically relevant;
- x. symptomatic superficial veins / varicosities (areas of pain and tenderness);
  - when identified, superficial venous thrombosis must be documented as:
    - o name of the involved vein;
    - tributary involvement, if any;
    - thrombus distance from the saphenofemoral junction/ saphenopopliteal junction;
    - o additional images (e.g., length of thrombus); as required by the protocol.

#### (See Guidelines on Page 53 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;
    - If common femoral vein thrombus is visualized or asymmetrical common femoral vein spectral Doppler is present, the examination should include iliac veins.
  - ii. popliteal vein;
  - iii. additional waveforms if required by the protocol.

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

#### (See Guidelines on Page 53 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. proximal femoral vein;
    - iv. mid femoral vein:
    - v. distal femoral vein;
    - vi. great saphenous vein;
    - vii. popliteal vein;
    - viii. small saphenous vein;
    - ix. additional images to document areas of suspected reflux and as required by the protocol.

- 4.7.2.2B Spectral Doppler waveforms with the extremity(s) in a dependent position, demonstrating baseline flow and response to distal augmentation. If present, reflux duration of retrograde flow must be measured with calipers and documented as required by the protocol and must include at a minimum:
  - i. common femoral vein;
  - ii. saphenofemoral junction;
  - iii. great saphenous vein at proximal thigh;
  - iv. great saphenous vein at knee;
  - v. great saphenous vein below the knee;
  - vi. femoral vein mid thigh;
  - vii. popliteal vein;
  - viii. anterior accessory saphenous vein (when identified);
  - ix. small saphenous vein at junction of the deep system (when visualized);
  - x. small saphenous vein at mid calf;
  - xi. perforator vein waveforms in the setting of active or healed venous ulcers, as required by the protocol;
  - xii. additional waveforms as required by the protocol.

#### (See Guidelines on Page 53 for further recommendations.)

- 4.7.2.3B Transverse grayscale images of diameter measurement must be documented with the extremity(s) in a dependent position and must include at a minimum:
  - i. saphenofemoral junction;
  - ii. great saphenous vein at proximal thigh;
  - iii. great saphenous vein at knee;
  - iv. anterior accessory saphenous vein (when identified);
  - v. small saphenous vein at saphenopopliteal junction (when visualized). If not visualized there, the small saphenous vein at mid calf must be documented.
- 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 protocol.

- 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 protocol.

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

- 4.7.4B Vein mapping, if performed, must include:
  - 4.7.4.1B assessment of the veins, including tourniquet use as required by the protocol;
  - 4.7.4.2B vein patency and diameter.
- 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 Hemodialysis access arteriovenous fistulae (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 as required by the protocol.
  - 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;
    - v. subclavian vein as required by the protocol.

- 4.7.6.4B Blood flow volume must be documented from at least one site.
- 4.7.6.5B 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.

4.7.6.6B 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 the physician interpreting the examination.

## 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 maintenance 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 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 protocol, vein size measurements must be recorded.
- 4.7.1.2B, 4.7.2.1B Additional sites may be required by the 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 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 protocol or when indicated jugular/subclavian vein junction, brachiocephalic (innominate) vein or forearm veins.
  - When indicated or required by the protocol, vein size measurements must be recorded.
- 4.7.3.2B Additional sites may be required by the 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

#### 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 62 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
    - 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 62 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 <u>STANDARD Techniques</u>);

- 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 <a href="STANDARD Documentation">STANDARD Documentation</a>);
- 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.
- 5.3.6B Ultrasound contrast material may be utilized for examination of the visceral vessels and aortic endografts. Standard protocols regarding ultrasound contrast examination and off-label use must be described.

(See Guidelines on Page 62 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;
  - 5.4.6B abdominal agrta examination for aneurysm and/or stenosis (when present);
  - 5.4.7B aortic aneurysm following endovascular aneurysm repair.
- 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 stent(s) when present;
  - 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 <u>Mesenteric Arterial System</u>
    - 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;
      - v. stent(s) when present, including proximal and distal ends.

- 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;
  - vii. stent(s) when present.
    - native artery at the proximal end of the stent;
    - proximal stent;
    - mid stent;
    - distal stent;
    - native artery at the distal end of the stent.

#### 5.9.2B <u>Hepatoportal System</u>

- 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;
  - v. stent(s) when present, including proximal and distal ends.
- 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);
  - ix. stent(s) when visualized, must include:
    - native artery at the proximal end of the stent;
    - proximal stent;
    - mid stent;
    - distal stent;
    - native artery at the distal end of the stent.

Comment: Limitations of the study must be documented in the final report.

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 <u>Liver Transplant</u>

- 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 agrae examinations (if performed) must be documented as required by the protocol and must include at a minimum.
  - 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.

- 5.9.7B Abdominal aortic aneurysm following endovascular aneurysm repair (EVAR).
  - 5.9.7.1B Transverse view (defined as perpendicular to the long axis of the aorta, including endograft) 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;
    - v. position of endograft.
  - 5.9.7.2B 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 aortic aneurysm 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;
    - v. location of endograft including proximal and distal attachment sites and limb components.
  - 5.9.7.3B Color Doppler images and spectral Doppler waveforms and velocity measurements must be documented as required by the protocol and must include at a minimum:
    - i. aorta proximal to the endograft;
    - ii. proximal endograft;
    - iii. distal endograft;
    - iv. iliac limbs of the endograft;
    - v. outflow vessels distal to the endograft;
    - vi. the aneurysm sac outside of the endograft, including documentation of blood flow (endoleak) if identified;
    - vii. location and patency of branch vessels at the site(s) of intervention.
  - 5.9.7.4B Images following the administration of ultrasound contrast agents (if used) must be obtained in locations of identified or potential endoleaks.

5.9.7.5B The location of the proximal and distal points of graft attachment and type of endoleak (if identified) must be included in the final report. Results of secondary interventions, (placement of additional stent(s), embolization of endoleaks, etc.) must be included in reports of subsequent examination.

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

#### 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.

# 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 maintenance 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 <u>Imaging Equipment</u> 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:

- i. recording 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.

#### 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 <u>STANDARD Techniques</u>);
  - 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.

Comment: IAC strongly recommends use of the <u>IAC-modification to the SRU Consensus</u> Criteria for Interpretation of Internal Carotid Artery Stenosis.

#### 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.

# Section 6B: Screening Testing *Guidelines*

- 6.13B The annual procedure volume should be sufficient to maintain proficiency in examination 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

## **Section 1C: Quality Improvement Program**

#### STANDARD - QI Program

- 1.1C The facility must have a written Quality Improvement (QI) program to evaluate all types of procedures performed in the facility on an ongoing basis. The QI program must include the QI measures outlined below but may not be limited to the evaluation and review of:
  - 1.1.1C test appropriateness;
  - 1.1.2C technical quality and, if applicable, safety of the imaging;
  - 1.1.3C interpretive quality review;
  - 1.1.4C report completeness and timeliness; and
  - 1.1.5C case review.

#### STANDARD - QI Oversight

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

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

#### STANDARD - General QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C through 2.1.5C.

#### 2.1.1C <u>Test Appropriateness</u>

- 2.1.1.1C The facility must evaluate the appropriateness of the test performed and categorize as:
  - i. appropriate/usually appropriate;
  - ii. may be appropriate;
  - iii. rarely appropriate/usually not appropriate.

(See Guidelines on Page 70 for further recommendations.)

#### 2.1.2C <u>Technical Quality Review</u>

- 2.1.2.1C The facility must evaluate the technical quality and, if applicable, the safety of the test performed. The review must include but is not limited to the evaluation of:
  - i. the images/procedure data for suboptimal images/procedure data or artifact;
  - ii. completeness of the study; and
  - iii. adherence to the facility imaging/data acquisition protocols.

#### 2.1.3C <u>Interpretive Quality Review</u>

2.1.3.1C The facility must evaluate the quality and accuracy of the interpretation based on the acquired images/procedure data for all types of procedures performed in the facility.

#### 2.1.4C Final Report Completeness and Timeliness

2.1.4.1C The facility must evaluate the final report for completeness and timeliness as required in the Standards.

#### 2.1.5C Case Review

2.1.5.1C Case review with any appropriate imaging modality, surgical findings, clinical outcome or other comparison of a minimum of four cases annually with at least two cases per relevant testing area (extracranial, intracranial, arterial, venous, visceral, screening).

## Section 2C: Quality Improvement Measures Guidelines

2.1.1C	There should be a mechanism for education of referring physicians to improve the appropriateness of
	testing.

## **Section 3C: Quality Improvement Meetings**

#### **STANDARD – QI Meetings**

- 3.1C Quality Improvement (QI) Meetings
  - 3.1.1C The facility must have a minimum of two QI meetings per year, one of which is to review the results of the QI analyses and any additional QI-related topics.
  - 3.1.2C All staff must participate in at least one meeting per year.

## **Section 4C: Quality Improvement Documentation**

#### STANDARD - QI Documentation

- 4.1C QI Documentation and Record Retention
  - 4.1.1C The facility QI documentation must include but is not limited to:
    - 4.1.1.1C the data for all of the QI measures;
    - 4.1.1.2C minutes from the QI meetings; and
    - 4.1.1.3C participant list (may include remote participation and/or review of minutes).
  - 4.1.2C The QI documentation must be maintained and available for all appropriate personnel to review.

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