

Accreditation Program Manual

Endovascular Surgery Center of Excellence



Accreditation Council
for Surgical Quality

ACSQ

Table of Contents

CHAPTER 1 – INTRODUCTION	4
CHAPTER 2 - INITIATIVES.....	5
2.1 Center of Excellence Accreditation Initiative:	5
2.2 HMO/Insurance Providers	6
CHAPTER 3 - ACCREDITATION PROGRAM – ENDOVASCULAR SURGERY CENTER OF EXCELLENCE® (ESCOE)	7
3.1 Purpose	7
3.2 Who must be accredited?	7
3.3 Eligibility	7
3.4 Expectations	7
3.5 Timeframe	7
CHAPTER 4 - HOSPITAL-BASED PROGRAMS.....	8
4.1 Eligibility	8
4.2 Accreditation Process	8
4.3 Conditional Status Application	9
4.4 Full Approval	26
4.5 Process - Conditional Status	27
4.6 Process - Full Approval	28
4.7 Site Inspection	29
4.8 Fee Structure	30
CHAPTER 5 – FREESTANDING OUTPATIENT PROGRAMS.....	32
5.1 Eligibility	32
5.2 Accreditation Process	32
5.3 Conditional Status Application	33
5.4 Full Approval	49
5.5 Process - Conditional Status	51
5.6 Process - Full Approval	51

5.7	Site Inspection	53
5.8	Fee Structure	53
CHAPTER 6 - INTERNATIONAL-PROGRAMS		56
6.1	Eligibility	56
6.2	Accreditation Process	56
6.3	Conditional Status Application	57
6.4	Full Approval	74
6.5	Process - Conditional Status	75
6.6	Process - Full Approval	75
6.7	Site Inspection	77
6.8	Fee Structure	77
CHAPTER 7 - ACSQ POLICY ON CONFLICTS OF INTEREST AND CONFIDENTIALITY.....		81
7.1	Purpose	81
7.2	Responsibility	81
7.3	Policy Statement	81
7.4	Definitions	81
7.5	Required Disclosures	83
7.6	Board Member Disclosure of Conflicts	83
7.7	Committee Member Disclosure of Conflicts	83
7.8	Staff Disclosure of Conflicts	84
7.9	Volunteer Assessor Disclosure	84
7.10	Effect of Disclosure	84
7.11	Whistleblower Policies	84
7.12	Recordkeeping for Board and Committee Votes	85
7.13	Protection of Confidential Information	85
CHAPTER 8 - ACSQ CODE OF ETHICS AND BYLAWS		86
4.1	ACSQ Code of Ethics	86
CHAPTER 9 - ACSQ BYLAWS		87
1.1	Name	87
1.2	Purposes	87

1.3	Offices	87
1.4	Membership and Affiliation	88
1.5	Meeting of Members	89
1.6	Board of Directors	90
1.7	Officers	93
1.8	Committees	95
1.9	Sections of Individual Members	96
1.10	Termination of Membership	96
1.11	Miscellaneous	97
1.12	Amendments	98
1.13	Indemnification	98
1.14	Conditions and Limitations	98
CHAPTER 10 - ACSQ CODE OF ETHICS AND BYLAWS		100
a.	Intended Audience	100
b.	Usage of the ACSQ Brand	100
c.	Trademark License	101
d.	Limitation of Liability	101
e.	ACSQ Brand Style Guide	101
CHAPTER 11 – CONSULTATION SERVICES.....		103
11.1	Consultation Services	103
CHAPTER 12 – REFERENCES		104

CHAPTER 1 – INTRODUCTION

Improving surgical outcomes encompasses the dogma of today’s practicing surgeons and healthcare institutions. The collaboration of surgeons, researchers and healthcare institutions to develop common goals with the intent to improve our surgical outcomes is the tenant of the Accreditation Council for Surgical Quality (ACSQ). With over 34 million surgical procedures undertaken within the United States yearly¹ and far greater numbers worldwide, instituted standards to improve the quality of our surgical outcomes allows patients to obtain quality care benchmarks to standards of good practice and discern providers who practice beyond such standards as quality centers of excellence.

The Accreditation Council for Surgical Quality (ACSQ) is a independent, nonprofit organization governed by healthcare providers and is dedicated to the advancement of safety, efficacy and efficiency of surgical care worldwide. The ACSQ is the first of such organizations that provides the public with defined measures to establish quality of care afforded by a healthcare center based on research based initiatives to provide quality excellence within the delivery of healthcare. Such builds the philosophy to provide the necessary education and research based initiatives to improve the quality associated with key surgical procedures within well defined specialties.

ACSQ’s Accreditation Program strives to improve the efficacy, efficiency, safety and quality of surgical and related healthcare delivery. The Accreditation Program assesses the quality and operational systems in place within the facility. The basis for assessment includes compliance with Standards, Code of Federal Regulations and federal guidance documents.

This independent assessment of a facility’s operations helps the facility to prepare for other inspections and serves as a valuable tool to improve both compliance and operations. Accreditation is granted for the efficacy, efficiency, safety and quality of surgical and related healthcare.

CHAPTER 2 - INITIATIVES

ACSQ has developed a series of initiatives to develop ongoing programs designed to improve defined surgical healthcare measures:

2.1 **Center of Excellence Accreditation Initiative:**

ACSQ develops and accredits best-in-class surgery center of excellence programs to ensure the safest, highest quality care is delivered premised on efficacy, efficiency, safety and quality to surgical patients within defined surgical specialties. ACSQ manages the Endovascular Surgery Center of Excellence® (ESCOE), Venous Surgery Center of Excellence® (VCOE) and Cardiac Surgery Center of Excellence® (CCOE) designations in the US, Canada and globally.

ACSQ Center of Excellence programs provide a concise outcomes based definition of healthcare excellence, whose designation is awarded to both the physician and the facility at which invasive endovascular therapies are performed. Commitments to long-term patient care and focus on defined quality objectives by the physician and affiliated facility with a multidisciplinary approach underscores ACSQ's defined designation to ensure an extensive, research-based and verification system through rigorous site inspections and peer-reviewed standards.

ACSQ's Center of Excellence program ensures increase in patient care, referrals, data exchange, and collaborative clinical research quality outcomes in interventional invasive endovascular therapies.

Table 1. Benefits of ACSQ Accreditation

Strengthens community confidence in the quality and safety of care, treatment and services

Provides a competitive edge in the marketplace

Improves risk management and risk reduction

Provides education on good practices to improve business operations

Provides professional advice and counsel, enhancing staff education

Enhances staff recruitment and development

Recognized by insurers and various third parties

ACSQ Center of Excellence programs are the primary accreditation sought by hospitals, clinics, physicians and patients as a definitive source for obtaining markers of achievement and improving overall patient care, referrals, data exchange, and collaborative clinical research quality outcomes in invasive endovascular therapies. Such objectives underscore the need to have a healthy, successful body whose focus is solely on the improvement of healthcare and outcomes in surgery.

Table 2. ACSQ certification and accreditation geared towards

Hospitals – CEO, marketing directors, administration, individual surgeons and departmental groups

Independents/Stand-alone practices – CEO, administration, individual surgeons

Independent Surgeons – practicing board certified surgeons within the specialties identified by the ACSQ

Independent Interventional Radiologists – practicing board certified interventional radiologists within the specialties identified by the ACSQ

Independent Interventional Cardiologists – practicing board certified interventional cardiologists within the specialties identified by the ACSQ

HMO/Health Plan Initiatives – Administration and CEO

2.2 **HMO/Insurance Providers**

Recognizing the importance of quality initiatives and standards development allows for key initiatives for future development of support from insurance carriers and Medicare. Supporting accreditation allows for improved outcomes with reduced costs to ensure geographic centers of care that provide accredited care.

CHAPTER 3 - ACCREDITATION PROGRAM – ENDOVASCULAR SURGERY CENTER OF EXCELLENCE® (ESCOE)

The ACSQ program manual details the physical resources, human resources, clinical standards, credentialing of surgeons, data reporting standards and verification/approval processes for the Accreditation Council for Surgical Quality (ACSQ) Accreditation Program. The ACSQ Board of Directors may change or modify the processes, standards and stipulations set forth in this document as new knowledge, new technology and experience require.

3.1 **Purpose**

The purpose of the Accreditation Council for Surgical Quality (ACSQ) Accreditation Program is to evaluate an organization's practices to determine compliance with current applicable ACSQ Standards

3.2 **Who must be accredited?**

Accreditation is a requirement for all ACSQ Program Members. A new Program Member must complete the Initial Accreditation - Conditional Application before continuing with the Full Accreditation - Unconditional Application

3.3 **Eligibility**

- The facility must be in business 6 months or more prior to filing a Initial Accreditation - Conditional Application
- The facility must submit the 'Locations Table'. If multiple sites, additional fees may be require

3.4 **Expectations**

- Meet eligibility requirements
- All the standards are addressed in facility's policies, processes and procedures (PPPs)
- PPPs are followed as written

3.5 **Timeframe**

- The Initial Accreditation process usually takes a minimum of 6 months to complete

CHAPTER 4 - HOSPITAL-BASED PROGRAMS

4.1 **Eligibility**

Physicians and affiliated hospitals accredited as ACSQ Endovascular Surgery Center of Excellence® (ESCOE®) must undergo a process of evaluation designed to ensure the presence of a comprehensive interventional invasive endovascular therapies program that meets established program requirements for providing a safe interventional endovascular surgical environment with excellent short and long-term clinical outcomes. The evaluation process evaluates processes, i.e., equipment, supplies, training of physicians and staff and the availability of consultant services with specific emphasis on quality outcomes.

Application for designation as an ESCOE® is a voluntary process. The process begins with centers initially applying for a conditional status through an Initial Accreditation - Conditional Application process. Approval for Conditional Status is obtained when the institution can demonstrate the resources to provide a safe and effective interventional endovascular environment and delivery of care. A hospital or institution applicant that performs interventional invasive endovascular therapies at more than one location is required to submit a separate application for each geographically separated location. A “geographically separated location” is defined as a facility that is more than one mile apart. The requirement of separate applications applies even if the hospital or institution operates administratively as one entity and regardless of whether it has one federal employer identification number or one Medicare provider number.

4.2 **Accreditation Process**

A Initial Assessment - Conditional Accreditation Application must be submitted to initiate the ESCOE accreditation process. Initial Assessment - Conditional Accreditation Application are reviewed by the ACSQ Review Committee (ARC). Based upon the information provided by the applicant, centers and physicians may obtain one of the following designations:

Approved. Applicants who are approved may apply for Full Approval within two years via the Full Approval – Unconditional Application

Denied. Applicants who have been denied may correct their deficiencies and reapply after 6 months. Applicants may request that the application be reviewed again, or may appeal the decision to the Board of Directors

Review Status. Applicants under review status are designated when case volumes provided by an applicant are insufficient to maintain the required 125 cases per year (institution) or 50 cases per year/125 cases lifetime experience within the two-year Conditional Status period. Applicants are neither approved nor denied but instead are asked to report their volumes at 6 months for re-evaluation

Pending Status. Applicants with Pending Status are awaiting additional information as requested by the ARC for further determination

Conditional Status participants may apply for Full Approval once a determination has been made that the applicant has the experience necessary to provide a safe and effective

interventional endovascular environment and delivery of care based upon a comprehensive and independent review of their outcomes. Once the Full Approval application is received, a site inspection is conducted. Information collected during both the site inspection and from the Full Approval application is evaluated by the ARC. The Committee may then recommend one of the following designations:

Full Approval. This recommendation is forwarded to the ARC for final consideration and vote.

Denied. Applicants may request (1) that the application be reviewed again, (2) a second site inspection be conducted, and/or (3) an appeal to the Board of Directors. If denied, the institution will be reverted to a Conditional Status.

Pending Status. Reviewers may request additional information or request a second site visit

Probationary Status. Institutions that receive Conditional Status or Full Approval may lose that designation and be placed on Probationary Status when they no longer are able to meet the requirements set forth by the ACSQ. Failure to meet the standards after being reduced to Probationary Status within an acceptable period of time may result in a withdrawal of the designation. If the deficiencies are rectified within 6 months, Conditional Status or Full Approval will be reinstated.

Excellence in invasive endovascular therapies requires competent physician operators and well-prepared facilities. The application portfolio consists of two separate applications: one application submitted by each physician performing invasive endovascular procedures, and the second application submitted by the institution (hospital). Solo practitioners and physicians employed directly by hospitals or academic institutions must also complete and submit an individual application for physicians performing invasive endovascular procedures.

4.3 **Conditional Status Application**

The initial application is for Conditional Status designation. The application for Conditional Status focuses on:

- Resources of the applicant institution
- Training and experience of the surgeons and surgical group
- Determination of institutions reaching ACSQ objectives for Conditional Status designation

The ACSQ Review Committee (ARC) reviews all information submitted to determine whether defined parameters have been met. Information contained within the initial application is accepted on an honor system; site inspections for Conditional Status designations are required only on rare occasion when information contained within the application is unclear or suggests further verification. In cases of denial of the initial application, the applicant institution and the physician(s) are informed of the reason(s) for denial and invited to reapply when the deficiency(ies) are corrected.

The Conditional Status designation is for two years. Before that deadline, hospitals are encouraged to submit an application for Full Approval as an ACSQ Endovascular Surgery Center of Excellence® (ESCOE).

The requirements for Conditional Status are as follows:

1. Institutional Commitment to Excellence in Invasive endovascular therapies

A clear and defined institutional commitment further described within a institutions policies outlining the objectives of excellence in the care of vascular patients undergoing invasive endovascular therapies. Commitments detail documented ongoing, regularly scheduled, in-service education programs in invasive endovascular therapies. Institutional commitments additionally employ standards in credentialing guidelines for physicians performing invasive endovascular therapies detailed within medical staffing guidelines and institution's administration policies.

Hospitals must have a cross-organizational commitment to the care of vascular patients, from senior medical staff, administration and all staff who come into direct contact with vascular patients.

Importantly, hospitals must have defined vascular surgery credentialing and privileging guidelines that are clear and separate from general surgery guidelines.

Hospitals must also have ongoing, in-service education programs for staff who come into direct contact with vascular patients that are well-established and properly managed. These education programs must ensure a basic understanding of invasive endovascular therapies and concepts as well as the appropriate management and care of the vascular patient. The following in-services must be well-attended and documented:

Sensitivity training: in-service education must support a culture where staff members are prepared to manage vascular patients with an understanding and compassion and appreciate the burdens of the comorbidities present with vascular patients.

Signs and symptoms of postoperative complications: in-service education must help ensure that those directly caring for patients are able to recognize the potential signs and symptoms of common invasive endovascular therapies (e.g., pulmonary embolus, bleeding, infection and graft failure) such that vascular patients are managed promptly. Hospitals must also have a system in place to ensure the ongoing competencies of staff in recognizing these signs and symptoms.

The minimum frequency required for the above training is once every three

years for all relevant staff. However, most ESCOE hospitals provide this training every year and other programs are encouraged to do so as well. Training in these three areas is also required upon hiring for all new employees who will have direct contact with vascular patients.

2. Invasive Endovascular Experience and Volumes

Applicant institution has performed at least 125 endovascular surgical cases in the preceding 12-month period.

Each applicant physician performing invasive endovascular therapies has performed at least 125 total endovascular lifetime cases with at least 50 cases performed in the preceding 12-month period.

Physicians from several subspecialty backgrounds, such as cardiovascular medicine, vascular medicine, interventional radiology, and vascular surgery, have the interest and potential expertise to perform invasive endovascular procedures. The ability to perform catheter-based interventions safely and effectively requires specific knowledge about vascular biology and vascular diseases as well as technical skills. Knowledge about vascular biology and pathophysiology includes familiarity with the normal mechanisms that regulate blood vessel function and hemostasis, as well as the molecular and cellular processes that result in atherosclerosis and thrombosis, as previously discussed. Similarly, the interventionalist must possess the cognitive skills requisite to evaluate and treat patients with vascular diseases, especially occlusive diseases, aneurysmal disease, arterial dissection, and arterial and venous thromboembolism; this is because patients with these disorders constitute the majority of those referred for catheter-based interventions. The interventionalist should also be knowledgeable about less commonly encountered problems such as vasculitis and neurovascular compression syndromes. The vascular interventionalist should be able to interpret noninvasive vascular tests, such as pressure measurements, duplex ultrasound studies, computed tomography, and magnetic resonance angiography, because all of these modalities play a large role in catheter-based interventions. The interventionalist must understand the natural history of specific vascular diseases and be knowledgeable about the utility, accuracy, and limitations of diagnostic approaches, and be cognizant of the advantages, disadvantages, potential outcomes, and complications of all relevant diagnostic and therapeutic procedures.

Individuals performing catheter-based vascular interventions must be aware of the risk versus benefit ratio for each procedure. Indications and contraindications for interventions at each anatomic site must be clearly understood and considered in the context of the clinical scenario. The vascular interventionalist must be able to make judgments regarding the effect of local and general anesthesia and be knowledgeable about conscious sedation and the delivery of cardiorespiratory and hemodynamic support during the intervention. Also, the interventionalist should be familiar with the use of adjunctive

medications such as antiplatelet, antithrombotic, thrombolytic, vasodilator, and vasopressor drugs. Technical skills are mandatory for the timely performance of effective and safe endovascular procedures. Catheter based interventions require both knowledge of radiation physics and safety and skills in operating radiographic imaging equipment. The vascular interventionalist should be able to safely gain vascular access from multiple sites such as femoral (retrograde, antegrade, ipsilateral, and contralateral), popliteal (retrograde or antegrade), and upper extremity (axillary, brachial, and radial) arteries as well as from femoral, upper extremity (brachial), and neck (jugular) veins. Expertise includes the ability to perform and interpret high-quality diagnostic angiography utilizing both nonselective and selective techniques and to execute the technical aspects of endovascular procedures. Knowledge and expertise regarding methods to achieve hemostasis and alternatives to manual compression such as compression devices and vascular closure devices are required. The vascular interventionalist must be able to choose and place appropriate interventional devices at the treatment site, retrieve them if necessary, and close access sites after the intervention. The interventionalist must be able to manipulate guidewires and catheters, be knowledgeable about placement of balloons and stents, and be able to size and deploy devices. The ability to recognize and to manage procedure-related complications such as access site complications (bleeding, arteriovenous fistula, pseudoaneurysm, and infection), vessel rupture or occlusion, distal embolization, acute renal failure, and stent misdeployment and migration is required. The vascular interventionalist should be able to discuss results and recommendations for future care with the patient and family members, and to discharge the patient from the hospital with appropriate follow-up arrangements.

Training Requirements for Cardiovascular Physicians

The ACC Core Cardiology Training Symposium document provides guidelines for training in catheter-based peripheral interventions. For the fellow wishing to acquire competence as a peripheral vascular interventionalist, a minimum of 12 months of training is recommended. This period is in addition to the 24 months required for core cardiology training and at least 8 months acquiring experience in diagnostic cardiac catheterization in an ACGME-accredited fellowship program. It is recommended that the trainee perform 300 coronary diagnostic procedures, including 200 procedures with supervised primary responsibility prior to beginning interventional training. The trainee should participate in a minimum of 100 diagnostic peripheral angiograms and 50 noncardiac peripheral vascular interventional cases during the interventional training period. At least 50 of the diagnostic angiograms and 25 of the interventional cases should be as supervised primary operator. The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. Advanced training in peripheral vascular intervention can be undertaken concurrently with advanced training for coronary interventions. The year devoted to interventional training should include at least one month on an inpatient vascular medicine consultation service, one month in

a noninvasive vascular diagnostic laboratory, and one-half to one full day per week in the longitudinal care of outpatients with vascular disease.

Table 5. Formal Training to Achieve Competence in Peripheral Catheter-Based Interventions

Training requirements for cardiovascular physicians

- Duration of training*—12 months
- Diagnostic coronary angiograms†—300 cases (200 as the primary operator)
- Diagnostic peripheral angiograms—100 cases (50 as primary operator)
- Peripheral interventional cases§—50 cases (25 as primary operator)

Training requirements for interventional radiologists

- Duration of training‡—12 months
- Diagnostic peripheral angiograms—100 cases (50 as primary operator)
- Peripheral interventional cases§—50 cases (25 as primary operator)

Training requirements for vascular surgeons

- Duration of training—12 months
- Diagnostic peripheral angiograms¶—100 cases (50 as primary operator)
- Peripheral interventional cases§—50 cases (25 as primary operator)
- Aortic aneurysm endografts—10 cases (5 as primary operator)

This table is consistent with current Residency Review Committee requirements.

*After completing 24 months of core cardiovascular training and 8 months of cardiac catheterization. †Coronary catheterization procedures should be completed prior to interventional training. ‡After completing general radiology training. §The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. ¶In addition to 12 months of core vascular surgery training. In addition to experience gained during open surgical procedures.

Training Requirements for Interventional Radiologists

The pathway for interventional radiology training is completion of an ACGME-approved training program in vascular and interventional radiology. In addition, the interventional radiologist should be eligible for or have received the Certificate of Added Qualification (CAQ) given by the American Board of Radiology, as well as maintain recertification requirements. A minimum of 12 months of training in catheter-based intervention is required. This is in addition to the general radiology residency, which includes several months of interventional radiology. During the ACGME-approved fellowship, the trainee must have direct participation in a minimum of 500 procedures that encompass the full range of vascular and interventional procedures. The year devoted to interventional training should also include time dedicated to the clinical evaluation, treatment, and follow-up of patients with vascular disease and to noninvasive vascular evaluation, treatment, and follow-up of patients with vascular disease and to noninvasive vascular studies (e.g., ultrasound, magnetic resonance angiography, computed tomographic angiography, physiological arterial studies, stress tests). Upon completion of the fellowship, trainees that are

American Board of Radiology-certified in diagnostic radiology are CAQ eligible in vascular and interventional Radiology. At the time of CAQ examination, the trainee must have had documented direct participation in a minimum of 700 procedures, of which 100 are diagnostic angiograms (50 with supervised, primary responsibility), 50 are peripheral interventions (25 with supervised, primary responsibility), and 10 catheter-directed thrombolysis/thrombectomy. The case mix should be evenly distributed among the different vascular beds.

Training Requirements for Vascular Surgeons

Contemporary training in vascular surgery requires completion of an ACGME-accredited residency (Fellowship) after completion of an ACGME-accredited residency in surgery. Although the ACGME only requires one year for vascular surgery training, a second year is permitted and the vast majority of training programs are of two years' duration. The major components of vascular surgery training, in addition to performance of vascular operations, include inpatient and outpatient evaluation and management of patients with vascular diseases. This includes critical care management, and interpretation of noninvasive vascular diagnostic laboratory tests, angiograms, and other imaging modalities. The increasing importance and use of catheter based procedures has been recognized by the ACGME through its Residency Review Committee, which has made training in endovascular techniques a required component of vascular surgery programs. Therefore, training in peripheral catheter-based intervention is one of the major determinants for the second fellowship year. Vascular fellows may obtain this training in one year or throughout both years of a fellowship program. Vascular surgery fellows acquire unique and extensive experience with the manipulation of blood vessels during open surgical operations. Each trainee is required to perform a specified minimum number and type of open surgical procedures in different anatomic areas as the primary operating surgeon. Required numbers of endovascular procedures have not yet been implemented by the Residency Review Committee, but beginning in 2004, each vascular fellow will be required to perform a minimum of 100 diagnostic and 50 therapeutic endovascular procedures plus 5 to 10 aortic aneurysm endovascular grafting procedures. The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. These requirements are consistent with recommendations and guidelines for endovascular training and hospital credentialing developed and published by the American Association for Vascular Surgery and Society for Vascular Surgery.

Alternative Routes to Achieve Competence

Achieving competence in peripheral catheter-based procedures presents a significant challenge for established coronary interventionalists and vascular surgeons who have already completed training and are either board-certified or board-eligible in their subspecialty. Yet there are several compelling reasons to

encourage these individuals to achieve competence and to provide them with appropriate mechanisms to do so. Retraining practicing physicians can enhance their ability to deliver current and appropriate therapies to patients with vascular disease. Moreover, strategies to retrain often encourage healthy multidisciplinary interaction, teamwork, and exchange of knowledge among specialty groups. This collaboration benefits patient care and facilitates medical and scientific progress. Physicians who have previously completed training in interventional cardiology, vascular surgery, or interventional radiology already possess certain cognitive, technical, and clinical skills that provide a foundation for further training.²

Recognizing the need to balance the existing experience of these physicians with the need to acquire new skill sets, different pathways are possible and may be necessary to acquire competence in peripheral intervention. The particular pathway and requirements to achieve competence may vary for each individual, even among physicians from the same specialty, depending upon that physician's prior training and expertise. Ultimately, the cumulative knowledge base and expertise possessed by the interventionalist should be similar to those standards for new trainees outlined earlier in this document. It must be underscored that, to achieve procedural competence via alternative pathways, the vascular interventionalist must first acquire the cognitive and clinical knowledge requisite to understanding vascular diseases, including the fundamental biology, clinical manifestations, diagnostic tools, pharmacotherapies, and indications and contraindications to intervention.

Table 6. Alternative Routes to Achieving Competence in Peripheral Catheter-Based Intervention*

1. Common requirements
 - a. Completion of required training within 24-month period
 - b. Training under proctorship of formally trained vascular interventionalist competent to perform full range of procedures described in this document
 - c. Written curriculum with goals and objectives
 - d. Regular written evaluations by proctor
 - e. Documentation of procedures and outcomes
 - f. Supervised experience in inpatient and outpatient vascular consultation settings

 2. Procedural requirements for competency in all areas
 - a. Diagnostic peripheral angiograms—100 cases (50 as primary operator)
 - b. Peripheral interventions—50 cases (25 as primary operator)
 - c. No fewer than 20 diagnostic/10 interventional cases in each area, excluding extracranial cerebral arteries†
 - d. Extracranial cerebral (carotid/vertebral) arteries—30 diagnostic (15 as primary operator)/25 interventional (13 as primary operator)
 - e. Percutaneous thrombolysis/thrombectomy—5 cases

 3. Requirements for competency in subset of areas (up to 3, excluding carotid/vertebral arteries)
 - a. Diagnostic peripheral angiograms per area—30 cases (15 as primary operator)
 - b. Peripheral interventions per area—15 cases (8 as primary operator)
 - c. Must include aortoiliac arteries as initial area of competency
-

*The fulfillment of requirements via an alternative pathway is only appropriate if the candidate physician has the cognitive and technical skills outlined in Table 4 and is competent to perform either coronary intervention, interventional radiology, or vascular surgery. These alternative routes for achieving competency are available for up to 5 years following publication of this document. †Vascular areas are: 1) aortoiliac and brachiocephalic arteries; 2) abdominal visceral and renal arteries; and 3) infrainguinal arteries.

Knowledge of radiation physics and skills in operating imaging equipment is also necessary. Performance of at least 100 diagnostic peripheral angiograms, and no less than 50 peripheral interventional procedures, is required for competence as is the case for those participating in formal training programs. The physician should have been the primary operator for 25 of the peripheral angioplasty procedures. These procedures should be performed under the proctorship of a peripheral vascular interventionalist who is competent to perform the full range of procedures described in this document. A written curriculum with goals and objectives, regular written evaluations of the

physician by the proctor, and documentation of procedures with outcomes are required. The cases should be accumulated over a period of not more than 24 months. The physician should demonstrate evidence of adequate didactic and clinical training in the anatomy, pathophysiology, diagnosis, and medical management of peripheral vascular diseases and in endovascular techniques, which may be achieved by acquiring experience in supervised inpatient and outpatient vascular consultation settings, noninvasive vascular laboratories, and angiography/interventional laboratories. The physician should attend category 1 postgraduate education courses in peripheral vascular intervention, hospital conferences including endovascular mortality and morbidity, and document self-directed education. Appropriate documentation of the trainee's experience is required (see the following text). The case mix should be evenly distributed, so as to ensure exposure to diagnosis and intervention in a variety of different vascular beds.

Experience heavily weighted toward treatment of one specific site (e.g., renal) to the exclusion of other venues (e.g., infrainguinal) may not provide adequate expertise for the latter. To achieve a balanced experience required for competence, the physician's experience should include no fewer than 20 diagnostic/10 interventional individual supervised cases in each of the vascular territories described earlier in this document including: aortoiliac and brachiocephalic; abdominal visceral and renal; and infrainguinal. In addition, the physician should perform a minimum of five catheter-directed peripheral thrombolytic/ thrombectomy cases. Obtaining competence in the performance of procedures and interventions in the extracranial cerebral vessels (i.e., carotid and vertebral arteries) is considered a unique category on the following bases: first, although there is crossover in the technical skills from other vascular territories, unique challenges are associated with cannulating the carotid and vertebral arteries and performing interventions in these circulatory beds; and second, there are obvious special issues related to the distribution and target organ of these vessels, which allow for very narrow safety margins. For those performing carotid or vertebral procedures, suggested requirements for achievement of competence include mastery of the cognitive and clinical skills pertaining specifically to this vascular bed and these procedures. This includes, as with other sites, a complete understanding of the anatomical and pathological characteristics unique to this vascular bed and the ability to interpret relevant angiographic images. To achieve competence, a minimum of 30 diagnostic cerebrovascular angiograms, 15 as supervised primary operator, and a minimum of 25 supervised interventions, at least one-half as primary operator, should be performed, with appropriate documentation, follow-up, and outcomes assessment. The recommended number of procedures reflects the consensus of the expert opinion of the committee. It is acknowledged that catheter-based intervention of the extracranial cerebral arteries is an area of competence that is in evolution. Accordingly, these recommendations may be modified in future documents as experience and clinical evidence regarding its safety and efficacy is acquired. Also, as with procedures in other regional vascular venues, it is anticipated that for some physicians to achieve competence, supervising faculty

will recommend additional cases beyond the minimum number.

Physicians who have previously completed training in interventional cardiology or vascular surgery may elect to develop competence in only a subset of anatomic areas. Physicians who desire competence in more than three anatomic areas should pursue training for the full range of procedures in the manner outlined in the preceding paragraph. In order to maximize patient safety, physicians desiring competence in a subset of procedures require, as a minimum, proficiency in the aortoiliac arteries as the foundation for endovascular procedures in other anatomic beds. For physicians seeking to develop competence in a subset of procedures, no fewer than 30 diagnostic/15 interventional cases in any one anatomic area are necessary when seeking selective credentialing in a stepwise fashion, up to a maximum of 2 additional anatomic areas. Training should be performed under the proctorship of a peripheral vascular interventionalist who is credentialed to perform the full range of procedures described in this document. A written curriculum with goals and objectives, regular written evaluations of the physician by the proctor, and documentation of procedures with outcomes is required. The cases should be accumulated over a period of not more than 24 months. The physician should demonstrate evidence of adequate didactic and clinical training in the anatomy, pathophysiology, diagnosis, and medical management of peripheral vascular diseases and in endovascular techniques, which may be achieved by acquiring experience in supervised inpatient and outpatient vascular consultation settings, noninvasive vascular laboratories, and angiography/interventional laboratories.

The physician should attend category 1 postgraduate education courses in peripheral vascular intervention, hospital conferences including endovascular mortality and morbidity, and document self-directed education. In all of the situations described in the preceding text, clinical outcomes of procedures should be documented and comparable to published quality improvement guidelines for vascular interventions. In addition, after fulfilling initial requirements for competence, the log of cases should be continued for at least two years, with appropriate analysis of outcomes and quality assurance, to enable ongoing evaluation of competence.

Importantly, the numbers of procedures proposed in this document represent a minimum threshold for achieving competence. Certain individuals may require additional training to establish competence. Such individuals might include those who do not yet possess adequate basic catheter skills or those who, based on the dispassionate and objective evaluation of the supervising interventionalist, require additional instruction to achieve competence. Additionally, it is acknowledged that the training requirements outlined herein are designed to provide the physician with adequate exposure, knowledge, and judgment to recognize his or her limitations. Likewise, simply fulfilling the criteria described does not necessarily render the physician competent to perform any intervention in a given territory. Certain complex cases or pathological substrates may require that the physician obtain additional training

and supervision to achieve advanced levels of competence. These recommendations for alternative routes to achieve competency are put forward to enable physicians who have completed training in interventional cardiology, vascular surgery, or interventional radiology to acquire skills in procedures that were not part of their formal training program. However, the structure of current training programs in each discipline now permits interested physicians to acquire skills in catheter-based peripheral vascular interventions. Accordingly, it is recommended that alternative routes for achieving competency in catheter-based peripheral vascular interventions be available only for a period of five years following the publication of this document. Thereafter, it is expected that physicians wishing to acquire competency in this area do so through a formal training program as described earlier in this document.

Maintaining Competence

Maintenance of competence in catheter-based peripheral vascular interventions is an ongoing process that ensures continuity and growth of the cognitive, clinical, and technologic skills acquired during training. The physician's cognitive knowledge base in peripheral vascular disease 956 Creager et al. JACC Vol. 44, No. 4, 2004 ACC/ACP/SCAI/SVMB/SVS Clinical Competence Statement August 18, 2004:941–57 management and techniques must remain up-to-date. The physician must commit to ongoing education and life-long learning through documented attendance at continuing medical education seminars in the field of expertise, as well as demonstration of routine self-assessment. Technical skills should be maintained via performance of at least 25 peripheral vascular intervention cases annually and with documentation of favorable outcomes and minimal complications. Demonstration of continued competence must include documentation that applicable medical licensure in state, locale, region, or agency of practice has been maintained and is current. The physician must document that he/she has credentials and/or privileges in the specified areas of expertise at the local hospital and/or practice level. The physician must document appropriate board certification in his/her specific medical specialty or subspecialty as well as appropriate recertification.

Hospitals must have performed a minimum of 125 endovascular surgical cases in the preceding 12 months. Surgeons must have served as primary surgeon for at least 50 endovascular surgeries in the preceding 12 months and 200 during their lifetime of which 80 endovascular therapeutic procedures, 100 endovascular diagnostic procedures, and 20 endovascular aortic aneurysm repairs (EVAR)¹. If the surgeon's role as primary surgeon has been properly documented, 75 of the lifetime surgeries may have been performed during fellowship or residency. Cases in which the surgeon serves as co-surgeon or assisting surgeon do not count.

Only primary endovascular surgical procedures formally recognized by the SVS count toward the hospital and surgeon volume requirements. As of March 2009, the following procedures, the only primary procedures that qualify:

- EVAR
- Peripheral Endovascular Procedures
- Carotid Stenting

The following additional procedures also count toward the volume requirements:

- Catheter Directed Lysis
- Renal Artery Stenting

Procedures that do not count toward hospital and surgeon volume requirements include:

- Port placement
- Central line placement
- Diagnostic angiograms

Each hospital and surgeon procedure must be thoroughly documented to enable a medical chart review.

3. Designated Medical Director

Applicant maintains a designated physician Medical Director for invasive endovascular therapies who participates in the relevant administrative decision-making for the institution

Hospitals must have a designated physician medical director pertaining specifically to invasive endovascular therapies who participates in the interdisciplinary team meetings and is required to ensure that endovascular-related decisions are addressed in a comprehensive manner. Discussions held during these regularly scheduled meetings must be documented through minutes that demonstrate the medical director's involvement in key program decisions. The medical director must be a vascular surgeon, cardiologist or interventional radiologist who actively addresses medical staff, nursing, administration, central supply, operating room personnel and business issues related to the delivery of endovascular care to vascular patients.

The medical director must be an actively practicing physician with emphasis on invasive endovascular therapies – and meet all of the qualifications in Requirement 3 – if they are personally applying to the ESCOE program as one of the hospital's co-applicant interventionalist.\

However, the medical director does not need to be an actively practicing physician specializing in invasive endovascular therapies if they are not personally applying for or maintaining their ESCOE physicians designation.

The medical director must have been officially appointed through the facility's standard administrative/medical staff process, and cannot be self-appointed. Of note, this position can be filled with two co-medical directors.

4. Responsive Critical Care Support

The applicant hospital maintains, within 30 minutes of request, a full complement on staff of various consultative services required for the care of vascular patients undergoing invasive endovascular therapies including the immediate availability of an ACLS-qualified physician on-site who can perform patient resuscitations

If a vascular patient requires critical care, hospitals and their associated physicians must ensure that they receive appropriate care.

i) Consultants

Hospitals must maintain – and identify by name – on staff a full complement of consultative services and equipment required for the care of patients who undergo invasive endovascular therapies. At a minimum, this includes the following:

On-site 24/7: an advanced cardiac life support (ACLS)-qualified physician must be on-site at all times. This ensures that a qualified provider is able to perform patient resuscitations at any time in cases where anesthesia is not being given.

Of note, this coverage may be provided by a senior resident who holds ACLS certification. Hospitals with an emergency department can fulfill this requirement with a board-certified emergency room physician, as long as the hospital's policies dictate that this physician will be available at all times. This requirement may not be fulfilled with a nurse.

Four consultants who must be on-site within 30 minutes:

1. Anesthesiologist or certified registered nurse anesthetist (CRNA) who supervises anesthesia delivery on all vascular patients and is physically present while any of these patients is anesthetized
2. Vascular surgeons capable of performing operative interventions to manage complications
3. Interventionalist to diagnose complications

4. One physician with critical care credentials to manage complications: a critical care physician/intensivist, hospitalist, cardiologist or pulmonologist

Having an off-site intensive care unit (ICU) monitoring system (live video feed and remote vital sign monitoring) does not fulfill the need of having consultants physically on-site within 30 minutes.

Hospitals must also be able to identify by name other leading consultant support team members, including the vascular surgeon, cardiologist and pulmonologist. When applicable, this would also include an infectious disease specialist or nursing program manager.

- ii) Critical Care Equipment

Hospitals that have an ICU must have appropriate equipment, which is covered under Requirement 5. Hospitals that do not have an ICU on-site must be able to support critical care delivery. They must therefore have ventilators and hemodynamic monitoring equipment on-site so that qualified staff members are able to perform any necessary patient resuscitation.

- iii) Written Transfer Agreements

if applicable, hospitals must have a written transfer agreement that details the transfer plan of vascular surgery patients to other emergency or critical care facilities.

5. Appropriate Equipment and Instruments

Applicant maintains a full line of equipment and instruments for the care of vascular patients including comprehensive endovascular suite, wheel chairs, operating room tables, beds, radiologic capabilities, surgical instruments and other facilities suitable for the care of vascular patients.

Hospitals need to have a full line of equipment and instruments for the care of patients who undergo invasive endovascular therapies. This includes surgical/operating facilities and surgical instruments for vascular patients as well as appropriate radiological tables and facilities for evaluation, fluoroscopic technologies for endovascular imaging equipment for diagnostic purposes, and ICU equipment.

Additional required elements include chairs, beds, wheelchairs, examination and operating room tables, crash carts and stretchers/litters to accommodate vascular patients. Furniture and equipment must be able to accommodate patients that are within the mobile limits established by the invasive endovascular therapies program.

Appropriate patient movement/transfer systems must also be located wherever vascular surgery patients receive care. Personnel must be trained to use the

equipment and, most importantly, capable of moving these individuals without injury to the patient or themselves (see Requirement 1 regarding in-service education on patient transfers and mobilization).

Hospitals and surgical offices do not need to change all of the equipment, furniture and instruments throughout the entire facility. This requirement only applies to those areas where patients undergoing invasive endovascular therapies receive care. For some hospitals, this is a dedicated endovascular patient care area. For others, it occurs in several areas throughout the hospital.

6. Surgeon Dedication and Qualified Call Coverage

The applicant has a vascular surgeon who spends a significant portion of his or her efforts in the field of vascular surgery and who has qualified coverage and support for patient care.

Surgeons must be truly dedicated to vascular surgery, spending a significant portion of their efforts in the field and keeping current on techniques and literature. Surgeons must therefore be certified as vascular surgeons by the American Board of Vascular Surgery (ABS), American Osteopathic Board of Surgery (AOBS), or Royal College of Physicians and Surgeons of Canada (RCPSC).

Surgeons must have qualified coverage by a colleague who can be responsible for the complete care of a vascular patient – including the full range of complications associated with surgery of the vasculopath – in the absence of the primary surgeon.

Covering vascular surgeons must be board certified or eligible by the ABS, AOBS or RCPSC. They must also have at least 12 hours of Category 1 CME in vascular surgery every three years (half of the amount required for ESCOE designation).

All covering surgeons must be available on-site within 30 minutes. Surgeons and their covering surgeons who are not board certified will be considered on a case-by-case basis based on experience, demonstration of good standing, licensing and fellowship. This includes surgeons who have been board certified through credentialing bodies in other countries.

7. Clinical Pathways and Standard Operating Procedures

Applicant utilizes clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure.

Hospitals and surgeons must document and use clinical pathways and standardized orders to facilitate improved outcomes for the "uncomplicated patient" who undergoes invasive endovascular therapies. The interventionalist

decides which endovascular procedure(s) they will perform and what perioperative care will be. In turn, ACSQ requires that perioperative care details are well-documented and followed by the physician's team. Importantly, these standardized processes will also enable aggregate research on outcomes.

Clinical pathways, a sequence of orders and therapies describing the routine care of the uncomplicated patient from initial patient evaluation through long-term follow-up, must be established and clearly documented.

Clinical pathways must be developed for each procedure performed by the interventionalist and hospital. Within this, surgical pathways must detail the surgical technique for each surgeon and procedure. The standardized orders referenced in the clinical pathways must be similarly detailed and adhered to.

Clinical pathways can be documented in a variety of formats, including tables, algorithms/process maps and paragraph form. While consistency for each endovascular program is encouraged, it is not mandatory.

Clinical pathways must be formally adopted and implemented prior to the ACSQ site inspection. Nurses, physician assistants, residents, applicant physicians and other applicable staff must be aware of and following them.

Four clinical pathways are mandatory:

- Perioperative care, including monitoring and airway management
- Deep vein thrombosis (DVT) management
- Management of warning signs of complications such as tachycardia and hemorrhage

Ten of the following 11 clinical pathways are also required:

- Indications
- Contraindications
- Initial patient instruction
- Patient evaluation
- Laboratory studies
- Imaging studies
- Patient education/consent
- Admission workup and evaluation
- Preoperative and postoperative nutrition regimen
- Wound care management
- Pain management

8. Vascular Nurses, Physician Extenders and Program Coordinator

Applicant utilizes designated nurse or physician extenders who are dedicated to

servicing vascular patients and who are involved in continuing education in the care of vascular patients.

Hospitals and surgeons must create an invasive endovascular therapies program in which the non-physician staff members can manage day-to-day aspects in compliance with the ESCOE requirements, including the provision of patient education.

Nurses and physician extenders: hospitals must have designated surgical and nonsurgical nurses as well as physician extenders who serve endovascular surgical patients. These individuals must receive the ongoing in-service education outlined in Requirement 1.

Physician extenders are defined as any healthcare provider who assists an interventionalist.

Patient education: hospitals and surgeons should have nurses and physician extenders who provide education and care to vascular patients undergoing endovascular procedures.

Designated invasive endovascular therapies area: hospitals must have a dedicated vascular floor or designated cluster/group of beds that are maintained in a consistent area of the hospital. The area must be staffed with a team of dedicated vascular nurses and physician extenders.

Endovascular program coordinator: invasive endovascular programs must have a designated vascular coordinator who supervises program development, patient and staff education, ongoing ESCOE compliance and multidisciplinary team meetings. This person serves as the liaison between the affiliated hospital and endovascular practice(s).

A licensed health care professional must occupy the endovascular coordinator position full-time if the endovascular program handles more than 150 endovascular procedures annually or part-time if 150 or less. These duties can be split between two individuals, as long as one is a licensed health care professional.

9. Long-Term Patient Follow-Up

Applicant provides documentation of a program dedicated to a goal of long-term patient follow-up of at least 75 percent for endovascular procedures at five years with a monitoring and tracking system for outcomes, and agrees to provide surgical outcomes data on all patients in a manner consistent with Health Insurance Portability and Accountability Act (HIPAA) regulations.

Hospitals and surgeons must have a comprehensive long-term patient follow-up program that consistently monitors and tracks outcomes, complications and

comorbidities for all invasive endovascular therapies patients. The program must be designed with the goal of following up with 75% of all patients for five years or more after invasive endovascular therapies.

The long-term patient follow-up process must be thoroughly documented and identify which patients are included in follow-up (e.g., all patients, all operated patients or incomplete patient entry). This includes identification of the persons or entities responsible for follow-up, frequency and timing of post-discharge follow-up visits as well as formats and tools for tracking and documenting follow-up visits.

The responsible physician does not need to personally provide the follow-up. However, endovascular programs need to have mechanisms in place to follow the care if it is delivered by another/third party licensed or certified health care provider.

4.4 **Full Approval**

Prior to applying for Full Approval status, the Center must first have been granted Conditional Status. While Conditional Status is based on the adequacy of resources, Full Approval is based on the achievement of acceptable outcomes.

ACSQ anticipates developing additional guidelines and criteria for Full Approval based on outcomes data reported by program participants and by other databases. Future applications for Full Approval as well as renewal applications will be required to meet any outcomes data requirements and guidelines which may be in place at the time of application or renewal.

The application for Full Approval as an Accreditation Council of Surgical Quality (ACSQ) Center of Excellence® requests:

Information to assure that the requirements for Conditional Status remains satisfied.
Information regarding the patient populations, the operations performed, and their outcomes.

Full Approval requires a site inspection. The process is initiated once the application for Full Approval has been received by ACSQ. Nurses trained and experienced in invasive endovascular therapies who are full-time employees of ACSQ conduct the inspections following a prescribed protocol that includes:

- A careful review of the facilities.
- Interviews with the staff and key leaders of the facility.
- Random chart reviews.
- The purpose of the site inspection is to gather data, not to make judgments. The information collected during the site inspection is then submitted to Accreditation Council of Surgical Quality (ACSQ) for review with the Full Approval application. If the guidelines for Full Approval have been met, approval is granted for a term of three years.

Programs that fail to maintain standards may be placed on Probationary Status. If the deficits are not corrected or if there are egregious findings, the ACSQ may also recommend to the ACSQ review committee that the designation as a Endovascular Surgery Center of Excellence® be revoked.

If a program disagrees with the decisions of the ACSQ, it can appeal the matter to the Board of Directors.

The Full Approval application process to become an ACSQ Center of Excellence involves the following steps:

1. The center and its surgeons continue to meet the criteria required for Conditional Status and fully comply with the 9 requirements for Conditional Status.
2. Any deficiencies noted during the Conditional Status review have been corrected.
3. A complete and accurate description of changes in the institution or the staff (since the Conditional Status application) has been submitted to the ACSQ.
4. A list of the academic activities of the surgeons including grants obtained, papers published, presentations, participation in courses, etc. has been provided.
5. The surgeon must be, or must have been, board certified by either the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPSC).
6. Outcomes data for endovascular surgery are reported in accordance with HIPAA regulations.

4.5 **Process - Conditional Status**

The ACSQ Invasive endovascular therapies Centers of Excellence® program is a rigorous process designed to adequately determine those hospitals, surgeons and surgery centers that meet the established program requirements for providing excellent endovascular surgical care. The charts below detail each step of the application process to become an Endovascular Surgery Center of Excellence®.

4.6 **Process - Full Approval**

Prior to applying for Full Approval status, the Center must first have been granted Conditional Status. While Conditional Status is based on the adequacy of resources, Full Approval is based on the achievement of acceptable outcomes.

ACSQ anticipates developing additional guidelines and criteria for Full Approval as a freestanding outpatient Endovascular Surgery Center of Excellence® (ESCOE) based on outcomes data reported by program participants and by other databases. Future applications for Full Approval as well as renewal applications will be required to meet any outcomes data requirements and guidelines which may be in place at the time of application or renewal.

The application for Full Approval as a freestanding ACSQ ESCOE requests:

Information to assure that the requirements for Conditional Status remain satisfied.

Information regarding the patient populations, the operations performed, and their outcomes.

Full Approval requires a site inspection. The process is initiated once the application for Full Approval has been received. Nurses or allied health care professionals trained and experienced in endovascular surgery who are employees of ACSQ conduct the inspections following a prescribed protocol that includes:

A careful review of the facilities.

Interviews with the staff and key leaders of the facility.

Random chart reviews.

The purpose of the site inspection is to gather data, not to make judgments. The information collected during the site inspection is then submitted to the ACSQ Review Committee (ARC) for review with the Full Approval application. If the guidelines for Full Approval have been met, approval is granted for a term of three years.

Programs that fail to maintain standards may be placed on Probationary Status. If the deficits are not corrected or if there are egregious findings, the ACSQ may also recommend that the designation as a freestanding ESCOE be revoked.

If a program disagrees with the decisions of the ACSQ, it can appeal the matter to the Board of Directors.

The Full Approval application process to become a freestanding ACSQ ESCOE involves the following steps:

1. The center and its surgeons continue to meet the criteria required for Conditional Status and fully comply with the 13 requirements for Conditional Status.
2. Any deficiencies noted during the Conditional Status review have been corrected.
3. A complete and accurate description of changes in the institution or the staff (since the Conditional Status application) has been submitted to the ACSQ.
4. A list of the academic activities of the surgeons including grants obtained, papers published, presentations, participation in courses, etc. has been provided.
5. The surgeon must be, or must have been, board certified by either the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPSC).
6. Outcomes data for bariatric surgery are reported in an anonymous fashion in accordance with HIPAA regulations. Outcomes data must include a list of all bariatric surgical operations performed within the previous 12-month period including the following information (partial list):
 - Age
 - Gender
 - Weight
 - Height
 - BMI
 - Co-morbidities
 - Procedure
 - Length of Stay

Complications including mortality, re-admissions within 30 days of discharge, re-operations within 30 days after the initial operation

4.7 **Site Inspection**

The purpose of the site inspection is to verify that the information submitted in an application is accurate, and to substantiate and confirm that the requirements for Full Approval as a Bariatric Surgery Center of Excellence have been met. At the time the site inspection is scheduled, a detailed instruction letter and checklist will be sent to help with preparation for the inspection. The checklist will give details regarding the staff members and materials that will need to be assembled for the site inspectors.

Everything the site inspectors need to see will be included on the checklist; this is not a

surprise inspection. Gathering the necessary materials will facilitate a smoother inspection. Failure to provide the necessary materials could result in the termination of the inspection. For most Centers, site inspections will take approximately one day. However, if a Center has multiple surgeons and practices as co-applicants, it may take longer.

The site inspectors will not provide a determination or give advice during the inspection.

The information collected by the site inspectors is submitted to the ACSQ Review Committee (ARC) for evaluation. Based upon the site inspection findings and the information provided in the application, the ARC will make recommendations to the Board of Directors and will announce those Centers which it recognizes as Endovascular Surgery Centers of Excellence. A letter will be mailed informing Centers of the results.

From the date of the site inspection until the center is notified, the process normally takes approximately 90 days. If issues arise during the site inspection that require additional information to be obtained, this could lengthen the review process.

4.8 **Fee Structure**

ESCOE: United States & Canada

ACSQ values our participants' commitment to the ACSQ Endovascular Surgery Center of Excellence® (ASCOE) program. We listen to their feedback and are constantly improving our program based on this input. As a result, ACSQ has simplified our fee structure and significantly reduced the upfront costs of participation in the ESCOE program.

Facilities

Initial Application Fee: \$7,500

Facilities pay an initial application fee of \$7,500, which includes one year of participation

Annual Participation Fee: \$3,975

Surgeons

Initial Application Fee: \$500

Surgeons pay an initial application fee of \$500

Annual ESCOE Participation Fee: \$500

Practices

The surgical practice linked with the surgeon(s) and facility applying for designation does not pay any additional or separate fees.

Site Inspection

Site Inspection Fee: \$1,850

The site inspection fee is invoiced when the site inspection is scheduled. Additional site inspection fees will be billed at the completion of the site inspection if the inspection requires more than one site inspector and/or more than one site inspection day.

Methods of Payment

Fees must be paid by check or credit card. A Credit Card Payment Form (and a W-9 Form if needed) can be requested by contacting ACSQ Support at +1.866.790.4772 (US and Canada) or support@acsq.org. All payments should include your ACSQ ID number, name of the facility or surgeon, and applicable invoice number.

Credit card: Payments are not accepted over the phone and require a Credit Card Payment Form with an authorized signature (electronic signatures are not accepted). Forms should be faxed to the attention of Accounting at 1.617.869.4141.

Check: Funds must be drawn from a US account. ACSQ does not accept checks drawn on a foreign account.

Fees paid by check should be made payable to Accreditation Council for Surgical Quality and mailed to:

CHAPTER 5 – FREESTANDING OUTPATIENT PROGRAMS

5.1 **Eligibility**

Physicians and affiliated hospitals accredited as ACSQ Endovascular Surgery Center of Excellence® (ESCOE®) must undergo a process of evaluation designed to ensure the presence of a comprehensive interventional invasive endovascular therapies program that meets established program requirements for providing a safe interventional endovascular surgical environment with excellent short and long-term clinical outcomes. The evaluation process evaluates processes, i.e., equipment, supplies, training of physicians and staff and the availability of consultant services with specific emphasis on quality outcomes.

Application for designation as an ESCOE® is a voluntary process. The process begins with centers initially applying for a conditional status through an Initial Accreditation - Conditional Application process. Approval for Conditional Status is obtained when the institution can demonstrate the resources to provide a safe and effective interventional endovascular environment and delivery of care. A hospital or institution applicant that performs interventional invasive endovascular therapies at more than one location is required to submit a separate application for each geographically separated location. A “geographically separated location” is defined as a facility that is more than one mile apart. The requirement of separate applications applies even if the hospital or institution operates administratively as one entity and regardless of whether it has one federal employer identification number or one Medicare provider number.

5.2 **Accreditation Process**

A Initial Assessment - Conditional Accreditation Application must be submitted to initiate the ESCOE accreditation process. Initial Assessment - Conditional Accreditation Application are reviewed by the ACSQ Review Committee (ARC). Based upon the information provided by the applicant, centers and physicians may obtain one of the following designations:

Approved. Applicants who are approved may apply for Full Approval within two years via the Full Approval – Unconditional Application

Denied. Applicants who have been denied may correct their deficiencies and reapply after 6 months. Applicants may request that the application be reviewed again, or may appeal the decision to the Board of Directors

Review Status. Applicants under review status are designated when case volumes provided by an applicant are insufficient to maintain the required 125 cases per year (institution) or 50 cases per year/125 cases lifetime experience within the two-year Conditional Status period. Applicants are neither approved nor denied but instead are asked to report their volumes at 6 months for re-evaluation

Pending Status. Applicants with Pending Status are awaiting additional information as requested by the ARC for further determination

Conditional Status participants may apply for Full Approval once a determination has been made that the applicant has the experience necessary to provide a safe and effective

interventional endovascular environment and delivery of care based upon a comprehensive and independent review of their outcomes. Once the Full Approval application is received, a site inspection is conducted. Information collected during both the site inspection and from the Full Approval application is evaluated by the ARC. The Committee may then recommend one of the following designations:

Full Approval. This recommendation is forwarded to the ARC for final consideration and vote.

Denied. Applicants may request (1) that the application be reviewed again, (2) a second site inspection be conducted, and/or (3) an appeal to the Board of Directors. If denied, the institution will be reverted to a Conditional Status.

Pending Status. Reviewers may request additional information or request a second site visit

Probationary Status. Institutions that receive Conditional Status or Full Approval may lose that designation and be placed on Probationary Status when they no longer are able to meet the requirements set forth by the ACSQ. Failure to meet the standards after being reduced to Probationary Status within an acceptable period of time may result in a withdrawal of the designation. If the deficiencies are rectified within 6 months, Conditional Status or Full Approval will be reinstated.

Excellence in invasive endovascular therapies requires competent physician operators and well-prepared facilities. The application portfolio consists of two separate applications: one application submitted by each physician performing invasive endovascular procedures, and the second application submitted by the institution (hospital). Solo practitioners and physicians employed directly by hospitals or academic institutions must also complete and submit an individual application for physicians performing invasive endovascular procedures.

5.3 **Conditional Status Application**

The initial application is for Conditional Status designation. The application for Conditional Status focuses on:

- Resources of the applicant institution
- Training and experience of the surgeons and surgical group
- Determination of institutions reaching ACSQ objectives for Conditional Status designation

The ACSQ Review Committee (ARC) reviews all information submitted to determine whether defined parameters have been met. Information contained within the initial application is accepted on an honor system; site inspections for Conditional Status designations are required only on rare occasion when information contained within the application is unclear or suggests further verification. In cases of denial of the initial application, the applicant institution and the physician(s) are informed of the reason(s) for denial and invited to reapply when the deficiency(ies) are corrected.

The Conditional Status designation is for two years. Before that deadline, hospitals are encouraged to submit an application for Full Approval as an ACSQ Endovascular Surgery Center of Excellence® (ESCOE).

The requirements for Conditional Status are as follows:

1. Institutional Commitment to Excellence in Invasive endovascular therapies

A clear and defined institutional commitment further described within a institutions policies outlining the objectives of excellence in the care of vascular patients undergoing invasive endovascular therapies. Commitments detail documented ongoing, regularly scheduled, in-service education programs in invasive endovascular therapies. Institutional commitments additionally employ standards in credentialing guidelines for physicians performing invasive endovascular therapies detailed within medical staffing guidelines and institution's administration policies.

Hospitals must have a cross-organizational commitment to the care of vascular patients, from senior medical staff, administration and all staff who come into direct contact with vascular patients.

Importantly, hospitals must have defined vascular surgery credentialing and privileging guidelines that are clear and separate from general surgery guidelines.

Hospitals must also have ongoing, in-service education programs for staff who come into direct contact with vascular patients that are well-established and properly managed. These education programs must ensure a basic understanding of invasive endovascular therapies and concepts as well as the appropriate management and care of the vascular patient. The following in-services must be well-attended and documented:

Sensitivity training: in-service education must support a culture where staff members are prepared to manage vascular patients with an understanding and compassion and appreciate the burdens of the comorbidities present with vascular patients.

Signs and symptoms of postoperative complications: in-service education must help ensure that those directly caring for patients are able to recognize the potential signs and symptoms of common invasive endovascular therapies (e.g., pulmonary embolus, bleeding, infection and graft failure) such that vascular patients are managed promptly. Hospitals must also have a system in place to ensure the ongoing competencies of staff in recognizing these signs and symptoms.

The minimum frequency required for the above training is once every three years for all relevant staff. However, most ESCOE hospitals provide this

training every year and other programs are encouraged to do so as well. Training in these three areas is also required upon hiring for all new employees who will have direct contact with vascular patients.

2. Invasive Endovascular Experience and Volumes

Applicant institution has performed at least 125 endovascular surgical cases in the preceding 12-month period.

Each applicant physician performing invasive endovascular therapies has performed at least 125 total endovascular lifetime cases with at least 50 cases performed in the preceding 12-month period.

Physicians from several subspecialty backgrounds, such as cardiovascular medicine, vascular medicine, interventional radiology, and vascular surgery, have the interest and potential expertise to perform invasive endovascular procedures. The ability to perform catheter-based interventions safely and effectively requires specific knowledge about vascular biology and vascular diseases as well as technical skills. Knowledge about vascular biology and pathophysiology includes familiarity with the normal mechanisms that regulate blood vessel function and hemostasis, as well as the molecular and cellular processes that result in atherosclerosis and thrombosis, as previously discussed. Similarly, the interventionalist must possess the cognitive skills requisite to evaluate and treat patients with vascular diseases, especially occlusive diseases, aneurysmal disease, arterial dissection, and arterial and venous thromboembolism; this is because patients with these disorders constitute the majority of those referred for catheter-based interventions. The interventionalist should also be knowledgeable about less commonly encountered problems such as vasculitis and neurovascular compression syndromes. The vascular interventionalist should be able to interpret noninvasive vascular tests, such as pressure measurements, duplex ultrasound studies, computed tomography, and magnetic resonance angiography, because all of these modalities play a large role in catheter-based interventions. The interventionalist must understand the natural history of specific vascular diseases and be knowledgeable about the utility, accuracy, and limitations of diagnostic approaches, and be cognizant of the advantages, disadvantages, potential outcomes, and complications of all relevant diagnostic and therapeutic procedures.

Individuals performing catheter-based vascular interventions must be aware of the risk versus benefit ratio for each procedure. Indications and contraindications for interventions at each anatomic site must be clearly understood and considered in the context of the clinical scenario. The vascular interventionalist must be able to make judgments regarding the effect of local and general anesthesia and be knowledgeable about conscious sedation and the delivery of cardiorespiratory and hemodynamic support during the intervention. Also, the interventionalist should be familiar with the use of adjunctive medications such as antiplatelet, antithrombotic, thrombolytic, vasodilator, and

vasopressor drugs. Technical skills are mandatory for the timely performance of effective and safe endovascular procedures. Catheter based interventions require both knowledge of radiation physics and safety and skills in operating radiographic imaging equipment. The vascular interventionalist should be able to safely gain vascular access from multiple sites such as femoral (retrograde, antegrade, ipsilateral, and contralateral), popliteal (retrograde or antegrade), and upper extremity (axillary, brachial, and radial) arteries as well as from femoral, upper extremity (brachial), and neck (jugular) veins. Expertise includes the ability to perform and interpret high-quality diagnostic angiography utilizing both nonselective and selective techniques and to execute the technical aspects of endovascular procedures. Knowledge and expertise regarding methods to achieve hemostasis and alternatives to manual compression such as compression devices and vascular closure devices are required. The vascular interventionalist must be able to choose and place appropriate interventional devices at the treatment site, retrieve them if necessary, and close access sites after the intervention. The interventionalist must be able to manipulate guidewires and catheters, be knowledgeable about placement of balloons and stents, and be able to size and deploy devices. The ability to recognize and to manage procedure-related complications such as access site complications (bleeding, arteriovenous fistula, pseudoaneurysm, and infection), vessel rupture or occlusion, distal embolization, acute renal failure, and stent misdeployment and migration is required. The vascular interventionalist should be able to discuss results and recommendations for future care with the patient and family members, and to discharge the patient from the hospital with appropriate follow-up arrangements.

Training Requirements for Cardiovascular Physicians

The ACC Core Cardiology Training Symposium document provides guidelines for training in catheter-based peripheral interventions. For the fellow wishing to acquire competence as a peripheral vascular interventionalist, a minimum of 12 months of training is recommended. This period is in addition to the 24 months required for core cardiology training and at least 8 months acquiring experience in diagnostic cardiac catheterization in an ACGME-accredited fellowship program. It is recommended that the trainee perform 300 coronary diagnostic procedures, including 200 procedures with supervised primary responsibility prior to beginning interventional training. The trainee should participate in a minimum of 100 diagnostic peripheral angiograms and 50 noncardiac peripheral vascular interventional cases during the interventional training period. At least 50 of the diagnostic angiograms and 25 of the interventional cases should be as supervised primary operator. The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. Advanced training in peripheral vascular intervention can be undertaken concurrently with advanced training for coronary interventions. The year devoted to interventional training should include at least one month on an inpatient vascular medicine consultation service, one month in a noninvasive vascular diagnostic laboratory, and one-half to one full day per

week in the longitudinal care of outpatients with vascular disease.

Table 5. Formal Training to Achieve Competence in Peripheral Catheter-Based Interventions

Training requirements for cardiovascular physicians

- Duration of training*—12 months
- Diagnostic coronary angiograms†—300 cases (200 as the primary operator)
- Diagnostic peripheral angiograms—100 cases (50 as primary operator)
- Peripheral interventional cases§—50 cases (25 as primary operator)

Training requirements for interventional radiologists

- Duration of training‡—12 months
- Diagnostic peripheral angiograms—100 cases (50 as primary operator)
- Peripheral interventional cases§—50 cases (25 as primary operator)

Training requirements for vascular surgeons

- Duration of training—12 months
 - Diagnostic peripheral angiograms¶—100 cases (50 as primary operator)
 - Peripheral interventional cases§—50 cases (25 as primary operator)
 - Aortic aneurysm endografts—10 cases (5 as primary operator)
-

This table is consistent with current Residency Review Committee requirements.

*After completing 24 months of core cardiovascular training and 8 months of cardiac catheterization. †Coronary catheterization procedures should be completed prior to interventional training. ‡After completing general radiology training. §The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. ¶In addition to 12 months of core vascular surgery training. In addition to experience gained during open surgical procedures.

Training Requirements for Interventional Radiologists

The pathway for interventional radiology training is completion of an ACGME-approved training program in vascular and interventional radiology. In addition, the interventional radiologist should be eligible for or have received the Certificate of Added Qualification (CAQ) given by the American Board of Radiology, as well as maintain recertification requirements. A minimum of 12 months of training in catheter-based intervention is required. This is in addition to the general radiology residency, which includes several months of interventional radiology. During the ACGME-approved fellowship, the trainee must have direct participation in a minimum of 500 procedures that encompass the full range of vascular and interventional procedures. The year devoted to interventional training should also include time dedicated to the clinical evaluation, treatment, and follow-up of patients with vascular disease and to noninvasive vascular evaluation, treatment, and follow-up of patients with vascular disease and to noninvasive vascular studies (e.g., ultrasound, magnetic resonance angiography, computed tomographic angiography, physiological arterial studies, stress tests). Upon completion of the fellowship, trainees that are American Board of Radiology-certified in diagnostic radiology are CAQ eligible

in vascular and interventional Radiology. At the time of CAQ examination, the trainee must have had documented direct participation in a minimum of 700 procedures, of which 100 are diagnostic angiograms (50 with supervised, primary responsibility), 50 are peripheral interventions (25 with supervised, primary responsibility), and 10 catheter-directed thrombolysis/thrombectomy. The case mix should be evenly distributed among the different vascular beds.

Training Requirements for Vascular Surgeons

Contemporary training in vascular surgery requires completion of an ACGME-accredited residency (Fellowship) after completion of an ACGME-accredited residency in surgery. Although the ACGME only requires one year for vascular surgery training, a second year is permitted and the vast majority of training programs are of two years' duration. The major components of vascular surgery training, in addition to performance of vascular operations, include inpatient and outpatient evaluation and management of patients with vascular diseases. This includes critical care management, and interpretation of noninvasive vascular diagnostic laboratory tests, angiograms, and other imaging modalities. The increasing importance and use of catheter based procedures has been recognized by the ACGME through its Residency Review Committee, which has made training in endovascular techniques a required component of vascular surgery programs. Therefore, training in peripheral catheter-based intervention is one of the major determinants for the second fellowship year. Vascular fellows may obtain this training in one year or throughout both years of a fellowship program. Vascular surgery fellows acquire unique and extensive experience with the manipulation of blood vessels during open surgical operations. Each trainee is required to perform a specified minimum number and type of open surgical procedures in different anatomic areas as the primary operating surgeon. Required numbers of endovascular procedures have not yet been implemented by the Residency Review Committee, but beginning in 2004, each vascular fellow will be required to perform a minimum of 100 diagnostic and 50 therapeutic endovascular procedures plus 5 to 10 aortic aneurysm endovascular grafting procedures. The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. These requirements are consistent with recommendations and guidelines for endovascular training and hospital credentialing developed and published by the American Association for Vascular Surgery and Society for Vascular Surgery.

Alternative Routes to Achieve Competence

Achieving competence in peripheral catheter-based procedures presents a significant challenge for established coronary interventionalists and vascular surgeons who have already completed training and are either board-certified or board-eligible in their subspecialty. Yet there are several compelling reasons to encourage these individuals to achieve competence and to provide them with

appropriate mechanisms to do so. Retraining practicing physicians can enhance their ability to deliver current and appropriate therapies to patients with vascular disease. Moreover, strategies to retrain often encourage healthy multidisciplinary interaction, teamwork, and exchange of knowledge among specialty groups. This collaboration benefits patient care and facilitates medical and scientific progress. Physicians who have previously completed training in interventional cardiology, vascular surgery, or interventional radiology already possess certain cognitive, technical, and clinical skills that provide a foundation for further training.²

Recognizing the need to balance the existing experience of these physicians with the need to acquire new skill sets, different pathways are possible and may be necessary to acquire competence in peripheral intervention. The particular pathway and requirements to achieve competence may vary for each individual, even among physicians from the same specialty, depending upon that physician's prior training and expertise. Ultimately, the cumulative knowledge base and expertise possessed by the interventionalist should be similar to those standards for new trainees outlined earlier in this document. It must be underscored that, to achieve procedural competence via alternative pathways, the vascular interventionalist must first acquire the cognitive and clinical knowledge requisite to understanding vascular diseases, including the fundamental biology, clinical manifestations, diagnostic tools, pharmacotherapies, and indications and contraindications to intervention.

Table 6. Alternative Routes to Achieving Competence in Peripheral Catheter-Based Intervention*

1. Common requirements
 - a. Completion of required training within 24-month period
 - b. Training under proctorship of formally trained vascular interventionalist competent to perform full range of procedures described in this document
 - c. Written curriculum with goals and objectives
 - d. Regular written evaluations by proctor
 - e. Documentation of procedures and outcomes
 - f. Supervised experience in inpatient and outpatient vascular consultation settings

 2. Procedural requirements for competency in all areas
 - a. Diagnostic peripheral angiograms—100 cases (50 as primary operator)
 - b. Peripheral interventions—50 cases (25 as primary operator)
 - c. No fewer than 20 diagnostic/10 interventional cases in each area, excluding extracranial cerebral arteries†
 - d. Extracranial cerebral (carotid/vertebral) arteries—30 diagnostic (15 as primary operator)/25 interventional (13 as primary operator)
 - e. Percutaneous thrombolysis/thrombectomy—5 cases

 3. Requirements for competency in subset of areas (up to 3, excluding carotid/vertebral arteries)
 - a. Diagnostic peripheral angiograms per area—30 cases (15 as primary operator)
 - b. Peripheral interventions per area—15 cases (8 as primary operator)
 - c. Must include aortoiliac arteries as initial area of competency
-

*The fulfillment of requirements via an alternative pathway is only appropriate if the candidate physician has the cognitive and technical skills outlined in Table 4 and is competent to perform either coronary intervention, interventional radiology, or vascular surgery. These alternative routes for achieving competency are available for up to 5 years following publication of this document. †Vascular areas are: 1) aortoiliac and brachiocephalic arteries; 2) abdominal visceral and renal arteries; and 3) infrainguinal arteries.

Knowledge of radiation physics and skills in operating imaging equipment is also necessary. Performance of at least 100 diagnostic peripheral angiograms, and no less than 50 peripheral interventional procedures, is required for competence as is the case for those participating in formal training programs. The physician should have been the primary operator for 25 of the peripheral angioplasty procedures. These procedures should be performed under the proctorship of a peripheral vascular interventionalist who is competent to perform the full range of procedures described in this document. A written curriculum with goals and objectives, regular written evaluations of the

physician by the proctor, and documentation of procedures with outcomes are required. The cases should be accumulated over a period of not more than 24 months. The physician should demonstrate evidence of adequate didactic and clinical training in the anatomy, pathophysiology, diagnosis, and medical management of peripheral vascular diseases and in endovascular techniques, which may be achieved by acquiring experience in supervised inpatient and outpatient vascular consultation settings, noninvasive vascular laboratories, and angiography/interventional laboratories. The physician should attend category 1 postgraduate education courses in peripheral vascular intervention, hospital conferences including endovascular mortality and morbidity, and document self-directed education. Appropriate documentation of the trainee's experience is required (see the following text). The case mix should be evenly distributed, so as to ensure exposure to diagnosis and intervention in a variety of different vascular beds.

Experience heavily weighted toward treatment of one specific site (e.g., renal) to the exclusion of other venues (e.g., infrainguinal) may not provide adequate expertise for the latter. To achieve a balanced experience required for competence, the physician's experience should include no fewer than 20 diagnostic/10 interventional individual supervised cases in each of the vascular territories described earlier in this document including: aortoiliac and brachiocephalic; abdominal visceral and renal; and infrainguinal. In addition, the physician should perform a minimum of five catheter-directed peripheral thrombolytic/ thrombectomy cases. Obtaining competence in the performance of procedures and interventions in the extracranial cerebral vessels (i.e., carotid and vertebral arteries) is considered a unique category on the following bases: first, although there is crossover in the technical skills from other vascular territories, unique challenges are associated with cannulating the carotid and vertebral arteries and performing interventions in these circulatory beds; and second, there are obvious special issues related to the distribution and target organ of these vessels, which allow for very narrow safety margins. For those performing carotid or vertebral procedures, suggested requirements for achievement of competence include mastery of the cognitive and clinical skills pertaining specifically to this vascular bed and these procedures. This includes, as with other sites, a complete understanding of the anatomical and pathological characteristics unique to this vascular bed and the ability to interpret relevant angiographic images. To achieve competence, a minimum of 30 diagnostic cerebrovascular angiograms, 15 as supervised primary operator, and a minimum of 25 supervised interventions, at least one-half as primary operator, should be performed, with appropriate documentation, follow-up, and outcomes assessment. The recommended number of procedures reflects the consensus of the expert opinion of the committee. It is acknowledged that catheter-based intervention of the extracranial cerebral arteries is an area of competence that is in evolution. Accordingly, these recommendations may be modified in future documents as experience and clinical evidence regarding its safety and efficacy is acquired. Also, as with procedures in other regional vascular venues, it is anticipated that for some physicians to achieve competence, supervising faculty

will recommend additional cases beyond the minimum number.

Physicians who have previously completed training in interventional cardiology or vascular surgery may elect to develop competence in only a subset of anatomic areas. Physicians who desire competence in more than three anatomic areas should pursue training for the full range of procedures in the manner outlined in the preceding paragraph. In order to maximize patient safety, physicians desiring competence in a subset of procedures require, as a minimum, proficiency in the aortoiliac arteries as the foundation for endovascular procedures in other anatomic beds. For physicians seeking to develop competence in a subset of procedures, no fewer than 30 diagnostic/15 interventional cases in any one anatomic area are necessary when seeking selective credentialing in a stepwise fashion, up to a maximum of 2 additional anatomic areas. Training should be performed under the proctorship of a peripheral vascular interventionalist who is credentialed to perform the full range of procedures described in this document. A written curriculum with goals and objectives, regular written evaluations of the physician by the proctor, and documentation of procedures with outcomes is required. The cases should be accumulated over a period of not more than 24 months. The physician should demonstrate evidence of adequate didactic and clinical training in the anatomy, pathophysiology, diagnosis, and medical management of peripheral vascular diseases and in endovascular techniques, which may be achieved by acquiring experience in supervised inpatient and outpatient vascular consultation settings, noninvasive vascular laboratories, and angiography/interventional laboratories.

The physician should attend category 1 postgraduate education courses in peripheral vascular intervention, hospital conferences including endovascular mortality and morbidity, and document self-directed education. In all of the situations described in the preceding text, clinical outcomes of procedures should be documented and comparable to published quality improvement guidelines for vascular interventions. In addition, after fulfilling initial requirements for competence, the log of cases should be continued for at least two years, with appropriate analysis of outcomes and quality assurance, to enable ongoing evaluation of competence.

Importantly, the numbers of procedures proposed in this document represent a minimum threshold for achieving competence. Certain individuals may require additional training to establish competence. Such individuals might include those who do not yet possess adequate basic catheter skills or those who, based on the dispassionate and objective evaluation of the supervising interventionalist, require additional instruction to achieve competence. Additionally, it is acknowledged that the training requirements outlined herein are designed to provide the physician with adequate exposure, knowledge, and judgment to recognize his or her limitations. Likewise, simply fulfilling the criteria described does not necessarily render the physician competent to perform any intervention in a given territory. Certain complex cases or pathological substrates may require that the physician obtain additional training

and supervision to achieve advanced levels of competence. These recommendations for alternative routes to achieve competency are put forward to enable physicians who have completed training in interventional cardiology, vascular surgery, or interventional radiology to acquire skills in procedures that were not part of their formal training program. However, the structure of current training programs in each discipline now permits interested physicians to acquire skills in catheter-based peripheral vascular interventions. Accordingly, it is recommended that alternative routes for achieving competency in catheter-based peripheral vascular interventions be available only for a period of five years following the publication of this document. Thereafter, it is expected that physicians wishing to acquire competency in this area do so through a formal training program as described earlier in this document.

Maintaining Competence

Maintenance of competence in catheter-based peripheral vascular interventions is an ongoing process that ensures continuity and growth of the cognitive, clinical, and technologic skills acquired during training. The physician's cognitive knowledge base in peripheral vascular disease 956 Creager et al. JACC Vol. 44, No. 4, 2004 ACC/ACP/SCAI/SVMB/SVS Clinical Competence Statement August 18, 2004:941–57 management and techniques must remain up-to-date. The physician must commit to ongoing education and life-long learning through documented attendance at continuing medical education seminars in the field of expertise, as well as demonstration of routine self-assessment. Technical skills should be maintained via performance of at least 25 peripheral vascular intervention cases annually and with documentation of favorable outcomes and minimal complications. Demonstration of continued competence must include documentation that applicable medical licensure in state, locale, region, or agency of practice has been maintained and is current. The physician must document that he/she has credentials and/or privileges in the specified areas of expertise at the local hospital and/or practice level. The physician must document appropriate board certification in his/her specific medical specialty or subspecialty as well as appropriate recertification.

Hospitals must have performed a minimum of 125 endovascular surgical cases in the preceding 12 months. Surgeons must have served as primary surgeon for at least 50 endovascular surgeries in the preceding 12 months and 200 during their lifetime of which 80 endovascular therapeutic procedures, 100 endovascular diagnostic procedures, and 20 endovascular aortic aneurysm repairs (EVAR)². If the surgeon's role as primary surgeon has been properly documented, 75 of the lifetime surgeries may have been performed during fellowship or residency. Cases in which the surgeon serves as co-surgeon or assisting surgeon do not count.

Only primary endovascular surgical procedures formally recognized by the SVS count toward the hospital and surgeon volume requirements. As of March 2009, the following procedures, the only primary procedures that qualify:

- EVAR
- Peripheral Endovascular Procedures
- Carotid Stenting

The following additional procedures also count toward the volume requirements:

- Catheter Directed Lysis
- Renal Artery Stenting

Procedures that do not count toward hospital and surgeon volume requirements include:

- Port placement
- Central line placement
- Diagnostic angiograms

Each hospital and surgeon procedure must be thoroughly documented to enable a medical chart review. a medical chart review.

3. Designated Medical Director

Applicant maintains a designated physician Medical Director for invasive endovascular therapies who participates in the relevant administrative decision-making for the institution

Hospitals must have a designated physician medical director pertaining specifically to invasive endovascular therapies who participates in the interdisciplinary team meetings and is required to ensure that endovascular-related decisions are addressed in a comprehensive manner. Discussions held during these regularly scheduled meetings must be documented through minutes that demonstrate the medical director's involvement in key program decisions. The medical director must be a vascular surgeon, cardiologist or interventional radiologist who actively addresses medical staff, nursing, administration, central supply, operating room personnel and business issues related to the delivery of endovascular care to vascular patients.

The medical director must be an actively practicing physician with emphasis on invasive endovascular therapies – and meet all of the qualifications in Requirement 3 – if they are personally applying to the ESCOE program as one of the hospital's co-applicant interventionalist.\

However, the medical director does not need to be an actively practicing physician specializing in invasive endovascular therapies if they are not personally applying for or maintaining their ESCOE physicians designation.

The medical director must have been officially appointed through the facility's standard administrative/medical staff process, and cannot be self-appointed. Of note, this position can be filled with two co-medical directors.

4. Responsive Critical Care Support

The applicant hospital maintains, within 30 minutes of request, a full complement on staff of various consultative services required for the care of vascular patients undergoing invasive endovascular therapies including the immediate availability of an ACLS-qualified physician on-site who can perform patient resuscitations

If a vascular patient requires critical care, hospitals and their associated physicians must ensure that they receive appropriate care.

i) Critical Care Equipment

Free Standing Outpatient Programs that have an ICU must have appropriate equipment, which is covered under Requirement 5. Free Standing Outpatient Programs that do not have an ICU on-site must be able to support critical care delivery. They must therefore have ventilators and hemodynamic monitoring equipment on-site so that qualified staff members are able to perform any necessary patient resuscitation.

ii) Written Transfer Agreements

if applicable, Free Standing Outpatient Programs must have a written transfer agreement that details the transfer plan of vascular surgery patients to other emergency or critical care facilities.

5. Appropriate Equipment and Instruments

Applicant maintains a full line of equipment and instruments for the care of vascular patients including comprehensive endovascular suite, wheel chairs, operating room tables, beds, radiologic capabilities, surgical instruments and other facilities suitable for the care of vascular patients.

Free Standing Outpatient Programs need to have a full line of equipment and instruments for the care of patients who undergo invasive endovascular therapies. This includes surgical/operating facilities and surgical instruments for

vascular patients as well as appropriate radiological tables and facilities for evaluation, fluoroscopic technologies for endovascular imaging equipment for diagnostic purposes, and ICU equipment.

Additional required elements include chairs, beds, wheelchairs, examination and operating room tables, crash carts and stretchers/litters to accommodate vascular patients. Furniture and equipment must be able to accommodate patients that are within the mobile limits established by the invasive endovascular therapies program.

Appropriate patient movement/transfer systems must also be located wherever vascular surgery patients receive care. Personnel must be trained to use the equipment and, most importantly, capable of moving these individuals without injury to the patient or themselves (see Requirement 1 regarding in-service education on patient transfers and mobilization).

Free Standing Outpatient Programs and surgical offices do not need to change all of the equipment, furniture and instruments throughout the entire facility. This requirement only applies to those areas where patients undergoing invasive endovascular therapies receive care. For some Free Standing Outpatient Programs, this is a dedicated endovascular patient care area. For others, it occurs in several areas throughout the hospital.

6. Surgeon Dedication and Qualified Call Coverage

The applicant has a vascular surgeon who spends a significant portion of his or her efforts in the field of vascular surgery and who has qualified coverage and support for patient care.

Surgeons must be truly dedicated to vascular surgery, spending a significant portion of their efforts in the field and keeping current on techniques and literature. Surgeons must therefore be certified as vascular surgeons by the American Board of Vascular Surgery (ABS), American Osteopathic Board of Surgery (AOBS), or Royal College of Physicians and Surgeons of Canada (RCPSC).

Surgeons must have qualified coverage by a colleague who can be responsible for the complete care of a vascular patient – including the full range of complications associated with surgery of the vasculopath – in the absence of the primary surgeon.

Covering vascular surgeons must be board certified or eligible by the ABS, AOBS or RCPSC. They must also have at least 12 hours of Category 1 CME in vascular surgery every three years (half of the amount required for ESCOE designation).

All covering surgeons must be available on-site within 30 minutes.

Surgeons and their covering surgeons who are not board certified will be considered on a case-by-case basis based on experience, demonstration of good standing, licensing and fellowship. This includes surgeons who have been board certified through credentialing bodies in other countries.

7. Clinical Pathways and Standard Operating Procedures

Applicant utilizes clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure.

Hospitals and surgeons must document and use clinical pathways and standardized orders to facilitate improved outcomes for the "uncomplicated patient" who undergoes invasive endovascular therapies. The interventionalist decides which endovascular procedure(s) they will perform and what perioperative care will be. In turn, ACSQ requires that perioperative care details are well-documented and followed by the physician's team. Importantly, these standardized processes will also enable aggregate research on outcomes.

Clinical pathways, a sequence of orders and therapies describing the routine care of the uncomplicated patient from initial patient evaluation through long-term follow-up, must be established and clearly documented.

Clinical pathways must be developed for each procedure performed by the interventionalist and hospital. Within this, surgical pathways must detail the surgical technique for each surgeon and procedure. The standardized orders referenced in the clinical pathways must be similarly detailed and adhered to.

Clinical pathways can be documented in a variety of formats, including tables, algorithms/process maps and paragraph form. While consistency for each endovascular program is encouraged, it is not mandatory.

Clinical pathways must be formally adopted and implemented prior to the ACSQ site inspection. Nurses, physician assistants, residents, applicant physicians and other applicable staff must be aware of and following them.

Four clinical pathways are mandatory:

- Perioperative care, including monitoring and airway management
- Deep vein thrombosis (DVT) management
- Management of warning signs of complications such as tachycardia and hemorrhage

Ten of the following 11 clinical pathways are also required:

- Indications
- Contraindications

- Initial patient instruction
- Patient evaluation
- Laboratory studies
- Imaging studies
- Patient education/consent
- Admission workup and evaluation
- Preoperative and postoperative nutrition regimen
- Wound care management
- Pain management

8. Vascular Nurses, Physician Extenders and Program Coordinator

Applicant utilizes designated nurse or physician extenders who are dedicated to serving vascular patients and who are involved in continuing education in the care of vascular patients.

Hospitals and surgeons must create an invasive endovascular therapies program in which the non-physician staff members can manage day-to-day aspects in compliance with the ESCOE requirements, including the provision of patient education.

Nurses and physician extenders: hospitals must have designated surgical and nonsurgical nurses as well as physician extenders who serve endovascular surgical patients. These individuals must receive the ongoing in-service education outlined in Requirement 1.

Physician extenders are defined as any healthcare provider who assists an interventionalist.

Patient education: hospitals and surgeons should have nurses and physician extenders who provide education and care to vascular patients undergoing endovascular procedures.

Designated invasive endovascular therapies area: hospitals must have a dedicated vascular floor or designated cluster/group of beds that are maintained in a consistent area of the hospital. The area must be staffed with a team of dedicated vascular nurses and physician extenders.

Endovascular program coordinator: invasive endovascular programs must have a designated vascular coordinator who supervises program development, patient and staff education, ongoing ESCOE compliance and multidisciplinary team meetings. This person serves as the liaison between the affiliated hospital and endovascular practice(s).

A licensed health care professional must occupy the endovascular coordinator position full-time if the endovascular program handles more than 150

endovascular procedures annually or part-time if 150 or less. These duties can be split between two individuals, as long as one is a licensed health care professional.

9. Long-Term Patient Follow-Up

Applicant provides documentation of a program dedicated to a goal of long-term patient follow-up of at least 75 percent for endovascular procedures at five years with a monitoring and tracking system for outcomes, and agrees to provide surgical outcomes data on all patients in a manner consistent with Health Insurance Portability and Accountability Act (HIPAA) regulations.

Hospitals and surgeons must have a comprehensive long-term patient follow-up program that consistently monitors and tracks outcomes, complications and comorbidities for all invasive endovascular therapies patients. The program must be designed with the goal of following up with 75% of all patients for five years or more after invasive endovascular therapies.

The long-term patient follow-up process must be thoroughly documented and identify which patients are included in follow-up (e.g., all patients, all operated patients or incomplete patient entry). This includes identification of the persons or entities responsible for follow-up, frequency and timing of post-discharge follow-up visits as well as formats and tools for tracking and documenting follow-up visits.

The responsible physician does not need to personally provide the follow-up. However, endovascular programs need to have mechanisms in place to follow the care if it is delivered by another/third party licensed or certified health care provider.

10. Limitations

The Applicant maintains that their facility will agree to limit endovascular procedures performed as an outpatient or 23 hours, 59 minutes stay to procedures in low risk patients (defined as patients age less than 60, a Body Mass Index (BMI) of less than 55, an American Society of Anesthesiologists (ASA) classification of less than IV (four), and no previous history of deep venous thrombosis (DVT) or pulmonary embolism (PE).

Free Standing Outpatient Programs and surgeons must have limitations on the outpatient nature of invasive endovascular procedures. The goal is to protect patients and provide a safe environment for procedures to be undertaken in a setting that provides optimal quality care.

5.4 **Full Approval**

Prior to applying for Full Approval status, the Center must first have been granted

Conditional Status. While Conditional Status is based on the adequacy of resources, Full Approval is based on the achievement of acceptable outcomes.

ACSQ anticipates developing additional guidelines and criteria for Full Approval based on outcomes data reported by program participants and by other databases. Future applications for Full Approval as well as renewal applications will be required to meet any outcomes data requirements and guidelines which may be in place at the time of application or renewal.

The application for Full Approval as an Accreditation Council of Surgical Quality (ACSQ) Center of Excellence® requests:

Information to assure that the requirements for Conditional Status remains satisfied. Information regarding the patient populations, the operations performed, and their outcomes.

Full Approval requires a site inspection. The process is initiated once the application for Full Approval has been received by ACSQ. Nurses trained and experienced in invasive endovascular therapies who are full-time employees of ACSQ conduct the inspections following a prescribed protocol that includes:

- A careful review of the facilities.
- Interviews with the staff and key leaders of the facility.
- Random chart reviews.
- The purpose of the site inspection is to gather data, not to make judgments. The information collected during the site inspection is then submitted to Accreditation Council of Surgical Quality (ACSQ) for review with the Full Approval application. If the guidelines for Full Approval have been met, approval is granted for a term of three years.

Programs that fail to maintain standards may be placed on Probationary Status. If the deficits are not corrected or if there are egregious findings, the ACSQ may also recommend to the ACSQ review committee that the designation as a Endovascular Surgery Center of Excellence® be revoked.

If a program disagrees with the decisions of the ACSQ, it can appeal the matter to the Board of Directors.

The Full Approval application process to become an ACSQ Center of Excellence involves the following steps:

1. The center and its surgeons continue to meet the criteria required for Conditional Status and fully comply with the 9 requirements for Conditional Status.
2. Any deficiencies noted during the Conditional Status review have been corrected.
3. A complete and accurate description of changes in the institution or the staff (since

the Conditional Status application) has been submitted to the ACSQ.

4. A list of the academic activities of the surgeons including grants obtained, papers published, presentations, participation in courses, etc. has been provided.
5. The surgeon must be, or must have been, board certified by either the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPSC).
6. Outcomes data for endovascular surgery are reported in accordance with HIPAA regulations.

5.5 **Process - Conditional Status**

The ACSQ Invasive endovascular therapies Centers of Excellence® program is a rigorous process designed to adequately determine those hospitals, surgeons and surgery centers that meet the established program requirements for providing excellent endovascular surgical care. The charts below detail each step of the application process to become an Endovascular Surgery Center of Excellence®.

5.6 **Process - Full Approval**

Prior to applying for Full Approval status, the Center must first have been granted Conditional Status. While Conditional Status is based on the adequacy of resources, Full Approval is based on the achievement of acceptable outcomes.

ACSQ anticipates developing additional guidelines and criteria for Full Approval as a freestanding outpatient Endovascular Surgery Center of Excellence® (ESCOE) based on outcomes data reported by program participants and by other databases. Future applications for Full Approval as well as renewal applications will be required to meet any outcomes data requirements and guidelines which may be in place at the time of application or renewal.

The application for Full Approval as a freestanding ACSQ ESCOE requests:

Information to assure that the requirements for Conditional Status remain satisfied.

Information regarding the patient populations, the operations performed, and their outcomes.

Full Approval requires a site inspection. The process is initiated once the application for Full Approval has been received. Nurses or allied health care professionals trained and experienced in endovascular surgery who are employees of ACSQ conduct the inspections following a prescribed protocol that includes:

A careful review of the facilities.

Interviews with the staff and key leaders of the facility.

Random chart reviews.

The purpose of the site inspection is to gather data, not to make judgments. The information collected during the site inspection is then submitted to the ACSQ Review Committee (ARC) for review with the Full Approval application. If the guidelines for Full Approval have been met, approval is granted for a term of three years.

Programs that fail to maintain standards may be placed on Probationary Status. If the deficits are not corrected or if there are egregious findings, the ACSQ may also recommend that the designation as a freestanding ESCOE be revoked.

If a program disagrees with the decisions of the ACSQ, it can appeal the matter to the Board of Directors.

The Full Approval application process to become a freestanding ACSQ ESCOE involves the following steps:

1. The center and its surgeons continue to meet the criteria required for Conditional Status and fully comply with the 13 requirements for Conditional Status.
2. Any deficiencies noted during the Conditional Status review have been corrected.
3. A complete and accurate description of changes in the institution or the staff (since the Conditional Status application) has been submitted to the ACSQ.
4. A list of the academic activities of the surgeons including grants obtained, papers published, presentations, participation in courses, etc. has been provided.
5. The surgeon must be, or must have been, board certified by either the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPSC).
6. Outcomes data for bariatric surgery are reported in an anonymous fashion in accordance with HIPAA regulations. Outcomes data must include a list of all bariatric surgical operations performed within the previous 12-month period including the following information (partial list):
 - Age
 - Gender
 - Weight
 - Height
 - BMI

- Co-morbidities
- Procedure
- Length of Stay

Complications including mortality, re-admissions within 30 days of discharge, re-operations within 30 days after the initial operation

5.7 **Site Inspection**

The purpose of the site inspection is to verify that the information submitted in an application is accurate, and to substantiate and confirm that the requirements for Full Approval as a Bariatric Surgery Center of Excellence have been met. At the time the site inspection is scheduled, a detailed instruction letter and checklist will be sent to help with preparation for the inspection. The checklist will give details regarding the staff members and materials that will need to be assembled for the site inspectors.

Everything the site inspectors need to see will be included on the checklist; this is not a surprise inspection. Gathering the necessary materials will facilitate a smoother inspection. Failure to provide the necessary materials could result in the termination of the inspection. For most Centers, site inspections will take approximately one day. However, if a Center has multiple surgeons and practices as co-applicants, it may take longer.

The site inspectors will not provide a determination or give advice during the inspection.

The information collected by the site inspectors is submitted to the Bariatric Surgery Review Committee (BACSQ) for evaluation. Based upon the site inspection findings and the information provided in the application, the BACSQ will make recommendations to the American Society for Metabolic and Bariatric Surgery (ASMBS). The ASMBS will announce those Centers which it recognizes as Bariatric Surgery Centers of Excellence. A letter will be mailed informing Centers of the results.

From the date of the site inspection until the center is notified, the process normally takes approximately 90 days. If issues arise during the site inspection that require additional information to be obtained, this could lengthen the review process.

5.8 **Fee Structure**

ACSQ values our participants' commitment to the ACSQ Endovascular Surgery Center of Excellence® (ASCOE) program. We listen to their feedback and are constantly improving our program based on this input. As a result, ACSQ has simplified our fee structure and significantly reduced the upfront costs of participation in the ESCOE program.

Free-Standing Structure

Initial Application Fee: \$6,500

Facilities pay an initial application fee of \$6,500, which includes one year of participation

Annual Participation Fee: \$3,975

Surgeons

Initial Application Fee: \$500

Surgeons pay an initial application fee of \$500

Annual ESCOE Participation Fee: \$500

Practices

The surgical practice linked with the surgeon(s) and facility applying for designation does not pay any additional or separate fees.

Site Inspection

Site Inspection Fee: \$1,850

The site inspection fee is invoiced when the site inspection is scheduled. Additional site inspection fees will be billed at the completion of the site inspection if the inspection requires more than one site inspector and/or more than one site inspection day.

Methods of Payment

Fees must be paid by check or credit card. A Credit Card Payment Form (and a W-9 Form if needed) can be requested by contacting ACSQ Support at +1.866.790.4772 (US and Canada) or support@acsq.org. All payments should include your ACSQ ID number, name of the facility or surgeon, and applicable invoice number.

Credit card: Payments are not accepted over the phone and require a Credit Card Payment Form with an authorized signature (electronic signatures are not accepted). Forms should be faxed to the attention of Accounting at 1.617.869.4141.

Check: Funds must be drawn from a US account. ACSQ does not accept checks drawn on a foreign account.

Fees paid by check should be made payable to Accreditation Council for Surgical Quality and mailed to:

CHAPTER 6 - INTERNATIONAL-PROGRAMS

6.1 **Eligibility**

Physicians and affiliated hospitals accredited as ACSQ Endovascular Surgery Center of Excellence® (ESCOE®) must undergo a process of evaluation designed to ensure the presence of a comprehensive interventional invasive endovascular therapies program that meets established program requirements for providing a safe interventional endovascular surgical environment with excellent short and long-term clinical outcomes. The evaluation process evaluates processes, i.e., equipment, supplies, training of physicians and staff and the availability of consultant services with specific emphasis on quality outcomes.

Application for designation as an ESCOE® is a voluntary process. The process begins with centers initially applying for a conditional status through an Initial Accreditation - Conditional Application process. Approval for Conditional Status is obtained when the institution can demonstrate the resources to provide a safe and effective interventional endovascular environment and delivery of care. A hospital or institution applicant that performs interventional invasive endovascular therapies at more than one location is required to submit a separate application for each geographically separated location. A “geographically separated location” is defined as a facility that is more than one mile apart. The requirement of separate applications applies even if the hospital or institution operates administratively as one entity and regardless of whether it has one federal employer identification number or one Medicare provider number.

6.2 **Accreditation Process**

A Initial Assessment - Conditional Accreditation Application must be submitted to initiate the ESCOE accreditation process. Initial Assessment - Conditional Accreditation Application are reviewed by the ACSQ Review Committee (ARC). Based upon the information provided by the applicant, centers and physicians may obtain one of the following designations:

Approved. Applicants who are approved may apply for Full Approval within two years via the Full Approval – Unconditional Application

Denied. Applicants who have been denied may correct their deficiencies and reapply after 6 months. Applicants may request that the application be reviewed again, or may appeal the decision to the Board of Directors

Review Status. Applicants under review status are designated when case volumes provided by an applicant are insufficient to maintain the required 125 cases per year (institution) or 50 cases per year/125 cases lifetime experience within the two-year Conditional Status period. Applicants are neither approved nor denied but instead are asked to report their volumes at 6 months for re-evaluation

Pending Status. Applicants with Pending Status are awaiting additional information as requested by the ARC for further determination

Conditional Status participants may apply for Full Approval once a determination has been made that the applicant has the experience necessary to provide a safe and effective

interventional endovascular environment and delivery of care based upon a comprehensive and independent review of their outcomes. Once the Full Approval application is received, a site inspection is conducted. Information collected during both the site inspection and from the Full Approval application is evaluated by the ARC. The Committee may then recommend one of the following designations:

Full Approval. This recommendation is forwarded to the ARC for final consideration and vote.

Denied. Applicants may request (1) that the application be reviewed again, (2) a second site inspection be conducted, and/or (3) an appeal to the Board of Directors. If denied, the institution will be reverted to a Conditional Status.

Pending Status. Reviewers may request additional information or request a second site visit

Probationary Status. Institutions that receive Conditional Status or Full Approval may lose that designation and be placed on Probationary Status when they no longer are able to meet the requirements set forth by the ACSQ. Failure to meet the standards after being reduced to Probationary Status within an acceptable period of time may result in a withdrawal of the designation. If the deficiencies are rectified within 6 months, Conditional Status or Full Approval will be reinstated.

Excellence in invasive endovascular therapies requires competent physician operators and well-prepared facilities. The application portfolio consists of two separate applications: one application submitted by each physician performing invasive endovascular procedures, and the second application submitted by the institution (hospital). Solo practitioners and physicians employed directly by hospitals or academic institutions must also complete and submit an individual application for physicians performing invasive endovascular procedures.

6.3 **Conditional Status Application**

The initial application is for Conditional Status designation. The application for Conditional Status focuses on:

- Resources of the applicant institution
- Training and experience of the surgeons and surgical group
- Determination of institutions reaching ACSQ objectives for Conditional Status designation

The ACSQ Review Committee (ARC) reviews all information submitted to determine whether defined parameters have been met. Information contained within the initial application is accepted on an honor system; site inspections for Conditional Status designations are required only on rare occasion when information contained within the application is unclear or suggests further verification. In cases of denial of the initial application, the applicant institution and the physician(s) are informed of the reason(s) for denial and invited to reapply when the deficiency(ies) are corrected.

The Conditional Status designation is for two years. Before that deadline, hospitals are

encouraged to submit an application for Full Approval as an ACSQ Endovascular Surgery Center of Excellence® (ESCOE).

The requirements for Conditional Status are as follows:

1. Institutional Commitment to Excellence in Invasive endovascular therapies

A clear and defined institutional commitment further described within a institutions policies outlining the objectives of excellence in the care of vascular patients undergoing invasive endovascular therapies. Commitments detail documented ongoing, regularly scheduled, in-service education programs in invasive endovascular therapies. Institutional commitments additionally employ standards in credentialing guidelines for physicians performing invasive endovascular therapies detailed within medical staffing guidelines and institution's administration policies.

Hospitals must have a cross-organizational commitment to the care of vascular patients, from senior medical staff, administration and all staff who come into direct contact with vascular patients.

Importantly, hospitals must have defined vascular surgery credentialing and privileging guidelines that are clear and separate from general surgery guidelines.

Hospitals must also have ongoing, in-service education programs for staff who come into direct contact with vascular patients that are well-established and properly managed. These education programs must ensure a basic understanding of invasive endovascular therapies and concepts as well as the appropriate management and care of the vascular patient. The following in-services must be well-attended and documented:

Sensitivity training: in-service education must support a culture where staff members are prepared to manage vascular patients with an understanding and compassion and appreciate the burdens of the comorbidities present with vascular patients.

Signs and symptoms of postoperative complications: in-service education must help ensure that those directly caring for patients are able to recognize the potential signs and symptoms of common invasive endovascular therapies (e.g., pulmonary embolus, bleeding, infection and graft failure) such that vascular patients are managed promptly. Hospitals must also have a system in place to ensure the ongoing competencies of staff in recognizing these signs and symptoms.

The minimum frequency required for the above training is once every three years for all relevant staff. However, most ESCOE hospitals provide this training every year and other programs are encouraged to do so as well. Training

in these three areas is also required upon hiring for all new employees who will have direct contact with vascular patients.

2. Invasive Endovascular Experience and Volumes

Applicant institution has performed at least 125 endovascular surgical cases in the preceding 12-month period.

Each applicant physician performing invasive endovascular therapies has performed at least 125 total endovascular lifetime cases with at least 50 cases performed in the preceding 12-month period.

Physicians from several subspecialty backgrounds, such as cardiovascular medicine, vascular medicine, interventional radiology, and vascular surgery, have the interest and potential expertise to perform invasive endovascular procedures. The ability to perform catheter-based interventions safely and effectively requires specific knowledge about vascular biology and vascular diseases as well as technical skills. Knowledge about vascular biology and pathophysiology includes familiarity with the normal mechanisms that regulate blood vessel function and hemostasis, as well as the molecular and cellular processes that result in atherosclerosis and thrombosis, as previously discussed. Similarly, the interventionalist must possess the cognitive skills requisite to evaluate and treat patients with vascular diseases, especially occlusive diseases, aneurysmal disease, arterial dissection, and arterial and venous thromboembolism; this is because patients with these disorders constitute the majority of those referred for catheter-based interventions. The interventionalist should also be knowledgeable about less commonly encountered problems such as vasculitis and neurovascular compression syndromes. The vascular interventionalist should be able to interpret noninvasive vascular tests, such as pressure measurements, duplex ultrasound studies, computed tomography, and magnetic resonance angiography, because all of these modalities play a large role in catheter-based interventions. The interventionalist must understand the natural history of specific vascular diseases and be knowledgeable about the utility, accuracy, and limitations of diagnostic approaches, and be cognizant of the advantages, disadvantages, potential outcomes, and complications of all relevant diagnostic and therapeutic procedures.

Individuals performing catheter-based vascular interventions must be aware of the risk versus benefit ratio for each procedure. Indications and contraindications for interventions at each anatomic site must be clearly understood and considered in the context of the clinical scenario. The vascular interventionalist must be able to make judgments regarding the effect of local and general anesthesia and be knowledgeable about conscious sedation and the delivery of cardiorespiratory and hemodynamic support during the intervention. Also, the interventionalist should be familiar with the use of adjunctive medications such as antiplatelet, antithrombotic, thrombolytic, vasodilator, and vasopressor drugs. Technical skills are mandatory for the timely performance of

effective and safe endovascular procedures. Catheter based interventions require both knowledge of radiation physics and safety and skills in operating radiographic imaging equipment. The vascular interventionalist should be able to safely gain vascular access from multiple sites such as femoral (retrograde, antegrade, ipsilateral, and contralateral), popliteal (retrograde or antegrade), and upper extremity (axillary, brachial, and radial) arteries as well as from femoral, upper extremity (brachial), and neck (jugular) veins. Expertise includes the ability to perform and interpret high-quality diagnostic angiography utilizing both nonselective and selective techniques and to execute the technical aspects of endovascular procedures. Knowledge and expertise regarding methods to achieve hemostasis and alternatives to manual compression such as compression devices and vascular closure devices are required. The vascular interventionalist must be able to choose and place appropriate interventional devices at the treatment site, retrieve them if necessary, and close access sites after the intervention. The interventionalist must be able to manipulate guidewires and catheters, be knowledgeable about placement of balloons and stents, and be able to size and deploy devices. The ability to recognize and to manage procedure-related complications such as access site complications (bleeding, arteriovenous fistula, pseudoaneurysm, and infection), vessel rupture or occlusion, distal embolization, acute renal failure, and stent misdeployment and migration is required. The vascular interventionalist should be able to discuss results and recommendations for future care with the patient and family members, and to discharge the patient from the hospital with appropriate follow-up arrangements.

Training Requirements for Cardiovascular Physicians

The ACC Core Cardiology Training Symposium document provides guidelines for training in catheter-based peripheral interventions. For the fellow wishing to acquire competence as a peripheral vascular interventionalist, a minimum of 12 months of training is recommended. This period is in addition to the 24 months required for core cardiology training and at least 8 months acquiring experience in diagnostic cardiac catheterization in an ACGME-accredited fellowship program. It is recommended that the trainee perform 300 coronary diagnostic procedures, including 200 procedures with supervised primary responsibility prior to beginning interventional training. The trainee should participate in a minimum of 100 diagnostic peripheral angiograms and 50 noncardiac peripheral vascular interventional cases during the interventional training period. At least 50 of the diagnostic angiograms and 25 of the interventional cases should be as supervised primary operator. The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. Advanced training in peripheral vascular intervention can be undertaken concurrently with advanced training for coronary interventions. The year devoted to interventional training should include at least one month on an inpatient vascular medicine consultation service, one month in a noninvasive vascular diagnostic laboratory, and one-half to one full day per week in the longitudinal care of outpatients with vascular disease.

Table 5. Formal Training to Achieve Competence in Peripheral Catheter-Based Interventions

Training requirements for cardiovascular physicians

- Duration of training*—12 months
- Diagnostic coronary angiograms†—300 cases (200 as the primary operator)
- Diagnostic peripheral angiograms—100 cases (50 as primary operator)
- Peripheral interventional cases§—50 cases (25 as primary operator)

Training requirements for interventional radiologists

- Duration of training‡—12 months
- Diagnostic peripheral angiograms—100 cases (50 as primary operator)
- Peripheral interventional cases§—50 cases (25 as primary operator)

Training requirements for vascular surgeons

- Duration of training—12 months
- Diagnostic peripheral angiograms¶—100 cases (50 as primary operator)
- Peripheral interventional cases§—50 cases (25 as primary operator)
- Aortic aneurysm endografts—10 cases (5 as primary operator)

This table is consistent with current Residency Review Committee requirements.

*After completing 24 months of core cardiovascular training and 8 months of cardiac catheterization. †Coronary catheterization procedures should be completed prior to interventional training. ‡After completing general radiology training. §The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. ¶In addition to 12 months of core vascular surgery training. In addition to experience gained during open surgical procedures.

Training Requirements for Interventional Radiologists

The pathway for interventional radiology training is completion of an ACGME-approved training program in vascular and interventional radiology. In addition, the interventional radiologist should be eligible for or have received the Certificate of Added Qualification (CAQ) given by the American Board of Radiology, as well as maintain recertification requirements. A minimum of 12 months of training in catheter-based intervention is required. This is in addition to the general radiology residency, which includes several months of interventional radiology. During the ACGME-approved fellowship, the trainee must have direct participation in a minimum of 500 procedures that encompass the full range of vascular and interventional procedures. The year devoted to interventional training should also include time dedicated to the clinical evaluation, treatment, and follow-up of patients with vascular disease and to noninvasive vascular evaluation, treatment, and follow-up of patients with vascular disease and to noninvasive vascular studies (e.g., ultrasound, magnetic resonance angiography, computed tomographic angiography, physiological arterial studies, stress tests). Upon completion of the fellowship, trainees that are American Board of Radiology-certified in diagnostic radiology are CAQ eligible in vascular and interventional Radiology. At the time of CAQ examination, the trainee must have had documented direct participation in a minimum of 700

procedures, of which 100 are diagnostic angiograms (50 with supervised, primary responsibility), 50 are peripheral interventions (25 with supervised, primary responsibility), and 10 catheter-directed thrombolysis/thrombectomy. The case mix should be evenly distributed among the different vascular beds.

Training Requirements for Vascular Surgeons

Contemporary training in vascular surgery requires completion of an ACGME-accredited residency (Fellowship) after completion of an ACGME-accredited residency in surgery. Although the ACGME only requires one year for vascular surgery training, a second year is permitted and the vast majority of training programs are of two years' duration. The major components of vascular surgery training, in addition to performance of vascular operations, include inpatient and outpatient evaluation and management of patients with vascular diseases. This includes critical care management, and interpretation of noninvasive vascular diagnostic laboratory tests, angiograms, and other imaging modalities. The increasing importance and use of catheter based procedures has been recognized by the ACGME through its Residency Review Committee, which has made training in endovascular techniques a required component of vascular surgery programs. Therefore, training in peripheral catheter-based intervention is one of the major determinants for the second fellowship year. Vascular fellows may obtain this training in one year or throughout both years of a fellowship program. Vascular surgery fellows acquire unique and extensive experience with the manipulation of blood vessels during open surgical operations. Each trainee is required to perform a specified minimum number and type of open surgical procedures in different anatomic areas as the primary operating surgeon. Required numbers of endovascular procedures have not yet been implemented by the Residency Review Committee, but beginning in 2004, each vascular fellow will be required to perform a minimum of 100 diagnostic and 50 therapeutic endovascular procedures plus 5 to 10 aortic aneurysm endovascular grafting procedures. The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included. These requirements are consistent with recommendations and guidelines for endovascular training and hospital credentialing developed and published by the American Association for Vascular Surgery and Society for Vascular Surgery.

Alternative Routes to Achieve Competence

Achieving competence in peripheral catheter-based procedures presents a significant challenge for established coronary interventionalists and vascular surgeons who have already completed training and are either board-certified or board-eligible in their subspecialty. Yet there are several compelling reasons to encourage these individuals to achieve competence and to provide them with appropriate mechanisms to do so. Retraining practicing physicians can enhance their ability to deliver current and appropriate therapies to patients with vascular

disease. Moreover, strategies to retrain often encourage healthy multidisciplinary interaction, teamwork, and exchange of knowledge among specialty groups. This collaboration benefits patient care and facilitates medical and scientific progress. Physicians who have previously completed training in interventional cardiology, vascular surgery, or interventional radiology already possess certain cognitive, technical, and clinical skills that provide a foundation for further training.²

Recognizing the need to balance the existing experience of these physicians with the need to acquire new skill sets, different pathways are possible and may be necessary to acquire competence in peripheral intervention. The particular pathway and requirements to achieve competence may vary for each individual, even among physicians from the same specialty, depending upon that physician's prior training and expertise. Ultimately, the cumulative knowledge base and expertise possessed by the interventionalist should be similar to those standards for new trainees outlined earlier in this document. It must be underscored that, to achieve procedural competence via alternative pathways, the vascular interventionalist must first acquire the cognitive and clinical knowledge requisite to understanding vascular diseases, including the fundamental biology, clinical manifestations, diagnostic tools, pharmacotherapies, and indications and contraindications to intervention.

Table 6. Alternative Routes to Achieving Competence in Peripheral Catheter-Based Intervention*

1. Common requirements
 - g. Completion of required training within 24-month period
 - h. Training under proctorship of formally trained vascular interventionalist competent to perform full range of procedures described in this document
 - i. Written curriculum with goals and objectives
 - j. Regular written evaluations by proctor
 - k. Documentation of procedures and outcomes
 - l. Supervised experience in inpatient and outpatient vascular consultation settings

 2. Procedural requirements for competency in all areas
 - f. Diagnostic peripheral angiograms—100 cases (50 as primary operator)
 - g. Peripheral interventions—50 cases (25 as primary operator)
 - h. No fewer than 20 diagnostic/10 interventional cases in each area, excluding extracranial cerebral arteries†
 - i. Extracranial cerebral (carotid/vertebral) arteries—30 diagnostic (15 as primary operator)/25 interventional (13 as primary operator)
 - j. Percutaneous thrombolysis/thrombectomy—5 cases

 3. Requirements for competency in subset of areas (up to 3, excluding carotid/vertebral arteries)
 - d. Diagnostic peripheral angiograms per area—30 cases (15 as primary operator)
 - e. Peripheral interventions per area—15 cases (8 as primary operator)
 - f. Must include aortoiliac arteries as initial area of competency
-

*The fulfillment of requirements via an alternative pathway is only appropriate if the candidate physician has the cognitive and technical skills outlined in Table 4 and is competent to perform either coronary intervention, interventional radiology, or vascular surgery. These alternative routes for achieving competency are available for up to 5 years following publication of this document. †Vascular areas are: 1) aortoiliac and brachiocephalic arteries; 2) abdominal visceral and renal arteries; and 3) infrainguinal arteries.

Knowledge of radiation physics and skills in operating imaging equipment is also necessary. Performance of at least 100 diagnostic peripheral angiograms, and no less than 50 peripheral interventional procedures, is required for competence as is the case for those participating in formal training programs. The physician should have been the primary operator for 25 of the peripheral angioplasty procedures. These procedures should be performed under the proctorship of a peripheral vascular interventionalist who is competent to perform the full range of procedures described in this document. A written curriculum with goals and objectives, regular written evaluations of the

physician by the proctor, and documentation of procedures with outcomes are required. The cases should be accumulated over a period of not more than 24 months. The physician should demonstrate evidence of adequate didactic and clinical training in the anatomy, pathophysiology, diagnosis, and medical management of peripheral vascular diseases and in endovascular techniques, which may be achieved by acquiring experience in supervised inpatient and outpatient vascular consultation settings, noninvasive vascular laboratories, and angiography/interventional laboratories. The physician should attend category 1 postgraduate education courses in peripheral vascular intervention, hospital conferences including endovascular mortality and morbidity, and document self-directed education. Appropriate documentation of the trainee's experience is required (see the following text). The case mix should be evenly distributed, so as to ensure exposure to diagnosis and intervention in a variety of different vascular beds.

Experience heavily weighted toward treatment of one specific site (e.g., renal) to the exclusion of other venues (e.g., infrainguinal) may not provide adequate expertise for the latter. To achieve a balanced experience required for competence, the physician's experience should include no fewer than 20 diagnostic/10 interventional individual supervised cases in each of the vascular territories described earlier in this document including: aortoiliac and brachiocephalic; abdominal visceral and renal; and infrainguinal. In addition, the physician should perform a minimum of five catheter-directed peripheral thrombolytic/ thrombectomy cases. Obtaining competence in the performance of procedures and interventions in the extracranial cerebral vessels (i.e., carotid and vertebral arteries) is considered a unique category on the following bases: first, although there is crossover in the technical skills from other vascular territories, unique challenges are associated with cannulating the carotid and vertebral arteries and performing interventions in these circulatory beds; and second, there are obvious special issues related to the distribution and target organ of these vessels, which allow for very narrow safety margins. For those performing carotid or vertebral procedures, suggested requirements for achievement of competence include mastery of the cognitive and clinical skills pertaining specifically to this vascular bed and these procedures. This includes, as with other sites, a complete understanding of the anatomical and pathological characteristics unique to this vascular bed and the ability to interpret relevant angiographic images. To achieve competence, a minimum of 30 diagnostic cerebrovascular angiograms, 15 as supervised primary operator, and a minimum of 25 supervised interventions, at least one-half as primary operator, should be performed, with appropriate documentation, follow-up, and outcomes assessment. The recommended number of procedures reflects the consensus of the expert opinion of the committee. It is acknowledged that catheter-based intervention of the extracranial cerebral arteries is an area of competence that is in evolution. Accordingly, these recommendations may be modified in future documents as experience and clinical evidence regarding its safety and efficacy is acquired. Also, as with procedures in other regional vascular venues, it is anticipated that for some physicians to achieve competence, supervising faculty

will recommend additional cases beyond the minimum number.

Physicians who have previously completed training in interventional cardiology or vascular surgery may elect to develop competence in only a subset of anatomic areas. Physicians who desire competence in more than three anatomic areas should pursue training for the full range of procedures in the manner outlined in the preceding paragraph. In order to maximize patient safety, physicians desiring competence in a subset of procedures require, as a minimum, proficiency in the aortoiliac arteries as the foundation for endovascular procedures in other anatomic beds. For physicians seeking to develop competence in a subset of procedures, no fewer than 30 diagnostic/15 interventional cases in any one anatomic area are necessary when seeking selective credentialing in a stepwise fashion, up to a maximum of 2 additional anatomic areas. Training should be performed under the proctorship of a peripheral vascular interventionalist who is credentialed to perform the full range of procedures described in this document. A written curriculum with goals and objectives, regular written evaluations of the physician by the proctor, and documentation of procedures with outcomes is required. The cases should be accumulated over a period of not more than 24 months. The physician should demonstrate evidence of adequate didactic and clinical training in the anatomy, pathophysiology, diagnosis, and medical management of peripheral vascular diseases and in endovascular techniques, which may be achieved by acquiring experience in supervised inpatient and outpatient vascular consultation settings, noninvasive vascular laboratories, and angiography/interventional laboratories.

The physician should attend category 1 postgraduate education courses in peripheral vascular intervention, hospital conferences including endovascular mortality and morbidity, and document self-directed education. In all of the situations described in the preceding text, clinical outcomes of procedures should be documented and comparable to published quality improvement guidelines for vascular interventions. In addition, after fulfilling initial requirements for competence, the log of cases should be continued for at least two years, with appropriate analysis of outcomes and quality assurance, to enable ongoing evaluation of competence.

Importantly, the numbers of procedures proposed in this document represent a minimum threshold for achieving competence. Certain individuals may require additional training to establish competence. Such individuals might include those who do not yet possess adequate basic catheter skills or those who, based on the dispassionate and objective evaluation of the supervising interventionalist, require additional instruction to achieve competence. Additionally, it is acknowledged that the training requirements outlined herein are designed to provide the physician with adequate exposure, knowledge, and judgment to recognize his or her limitations. Likewise, simply fulfilling the criteria described does not necessarily render the physician competent to perform any intervention in a given territory. Certain complex cases or pathological substrates may require that the physician obtain additional training

and supervision to achieve advanced levels of competence. These recommendations for alternative routes to achieve competency are put forward to enable physicians who have completed training in interventional cardiology, vascular surgery, or interventional radiology to acquire skills in procedures that were not part of their formal training program. However, the structure of current training programs in each discipline now permits interested physicians to acquire skills in catheter-based peripheral vascular interventions. Accordingly, it is recommended that alternative routes for achieving competency in catheter-based peripheral vascular interventions be available only for a period of five years following the publication of this document. Thereafter, it is expected that physicians wishing to acquire competency in this area do so through a formal training program as described earlier in this document.

Maintaining Competence

Maintenance of competence in catheter-based peripheral vascular interventions is an ongoing process that ensures continuity and growth of the cognitive, clinical, and technologic skills acquired during training. The physician's cognitive knowledge base in peripheral vascular disease 956 Creager et al. JACC Vol. 44, No. 4, 2004 ACC/ACP/SCAI/SVMB/SVS Clinical Competence Statement August 18, 2004:941–57 management and techniques must remain up-to-date. The physician must commit to ongoing education and life-long learning through documented attendance at continuing medical education seminars in the field of expertise, as well as demonstration of routine self-assessment. Technical skills should be maintained via performance of at least 25 peripheral vascular intervention cases annually and with documentation of favorable outcomes and minimal complications. Demonstration of continued competence must include documentation that applicable medical licensure in state, locale, region, or agency of practice has been maintained and is current. The physician must document that he/she has credentials and/or privileges in the specified areas of expertise at the local hospital and/or practice level. The physician must document appropriate board certification in his/her specific medical specialty or subspecialty as well as appropriate recertification.

Hospitals must have performed a minimum of 125 endovascular surgical cases in the preceding 12 months. Surgeons must have served as primary surgeon for at least 50 endovascular surgeries in the preceding 12 months and 200 during their lifetime of which 80 endovascular therapeutic procedures, 100 endovascular diagnostic procedures, and 20 endovascular aortic aneurysm repairs (EVAR)³. If the surgeon's role as primary surgeon has been properly documented, 75 of the lifetime surgeries may have been performed during fellowship or residency. Cases in which the surgeon serves as co-surgeon or assisting surgeon do not count.

Only primary endovascular surgical procedures formally recognized by the SVS count toward the hospital and surgeon volume requirements. As of March 2009, the following procedures, the only primary procedures that qualify:

- EVAR
- Peripheral Endovascular Procedures
- Carotid Stenting

The following additional procedures also count toward the volume requirements:

- Catheter Directed Lysis
- Renal Artery Stenting

Procedures that do not count toward hospital and surgeon volume requirements include:

- Port placement
- Central line placement
- Diagnostic angiograms

Each hospital and surgeon procedure must be thoroughly documented to enable a medical chart review. a medical chart review.

3. Designated Medical Director

Applicant maintains a designated physician Medical Director for invasive endovascular therapies who participates in the relevant administrative decision-making for the institution

Hospitals must have a designated physician medical director pertaining specifically to invasive endovascular therapies who participates in the interdisciplinary team meetings and is required to ensure that endovascular-related decisions are addressed in a comprehensive manner. Discussions held during these regularly scheduled meetings must be documented through minutes that demonstrate the medical director's involvement in key program decisions. The medical director must be a vascular surgeon, cardiologist or interventional radiologist who actively addresses medical staff, nursing, administration, central supply, operating room personnel and business issues related to the delivery of endovascular care to vascular patients.

The medical director must be an actively practicing physician with emphasis on invasive endovascular therapies – and meet all of the qualifications in Requirement 3 – if they are personally applying to the ESCOE program as one of the hospital's co-applicant interventionalist.\

However, the medical director does not need to be an actively practicing physician specializing in invasive endovascular therapies if they are not personally applying for or maintaining their ESCOE physicians designation.

The medical director must have been officially appointed through the facility's standard administrative/medical staff process, and cannot be self-appointed. Of note, this position can be filled with two co-medical directors.

4. Responsive Critical Care Support

The applicant hospital maintains, within 30 minutes of request, a full complement on staff of various consultative services required for the care of vascular patients undergoing invasive endovascular therapies including the immediate availability of an ACLS-qualified physician on-site who can perform patient resuscitations

If a vascular patient requires critical care, hospitals and their associated physicians must ensure that they receive appropriate care.

iii) Critical Care Equipment

Free Standing Outpatient Programs that have an ICU must have appropriate equipment, which is covered under Requirement 5. Free Standing Outpatient Programs that do not have an ICU on-site must be able to support critical care delivery. They must therefore have ventilators and hemodynamic monitoring equipment on-site so that qualified staff members are able to perform any necessary patient resuscitation.

iv) Written Transfer Agreements

if applicable, Free Standing Outpatient Programs must have a written transfer agreement that details the transfer plan of vascular surgery patients to other emergency or critical care facilities.

5. Appropriate Equipment and Instruments

Applicant maintains a full line of equipment and instruments for the care of vascular patients including comprehensive endovascular suite, wheel chairs, operating room tables, beds, radiologic capabilities, surgical instruments and other facilities suitable for the care of vascular patients.

Free Standing Outpatient Programs need to have a full line of equipment and instruments for the care of patients who undergo invasive endovascular therapies. This includes surgical/operating facilities and surgical instruments for

vascular patients as well as appropriate radiological tables and facilities for evaluation, fluoroscopic technologies for endovascular imaging equipment for diagnostic purposes, and ICU equipment.

Additional required elements include chairs, beds, wheelchairs, examination and operating room tables, crash carts and stretchers/litters to accommodate vascular patients. Furniture and equipment must be able to accommodate patients that are within the mobile limits established by the invasive endovascular therapies program.

Appropriate patient movement/transfer systems must also be located wherever vascular surgery patients receive care. Personnel must be trained to use the equipment and, most importantly, capable of moving these individuals without injury to the patient or themselves (see Requirement 1 regarding in-service education on patient transfers and mobilization).

Free Standing Outpatient Programs and surgical offices do not need to change all of the equipment, furniture and instruments throughout the entire facility. This requirement only applies to those areas where patients undergoing invasive endovascular therapies receive care. For some Free Standing Outpatient Programs, this is a dedicated endovascular patient care area. For others, it occurs in several areas throughout the hospital.

6. Surgeon Dedication and Qualified Call Coverage

The applicant has a vascular surgeon who spends a significant portion of his or her efforts in the field of vascular surgery and who has qualified coverage and support for patient care.

Surgeons must be truly dedicated to vascular surgery, spending a significant portion of their efforts in the field and keeping current on techniques and literature. Surgeons must therefore be certified as vascular surgeons by the American Board of Vascular Surgery (ABS), American Osteopathic Board of Surgery (AOBS), or Royal College of Physicians and Surgeons of Canada (RCPSC).

Surgeons must have qualified coverage by a colleague who can be responsible for the complete care of a vascular patient – including the full range of complications associated with surgery of the vasculopath – in the absence of the primary surgeon.

Covering vascular surgeons must be board certified or eligible by the ABS, AOBS or RCPSC. They must also have at least 12 hours of Category 1 CME in vascular surgery every three years (half of the amount required for ESCOE designation).

All covering surgeons must be available on-site within 30 minutes.

Surgeons and their covering surgeons who are not board certified will be considered on a case-by-case basis based on experience, demonstration of good standing, licensing and fellowship. This includes surgeons who have been board certified through credentialing bodies in other countries.

7. Clinical Pathways and Standard Operating Procedures

Applicant utilizes clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure.

Hospitals and surgeons must document and use clinical pathways and standardized orders to facilitate improved outcomes for the "uncomplicated patient" who undergoes invasive endovascular therapies. The interventionalist decides which endovascular procedure(s) they will perform and what perioperative care will be. In turn, ACSQ requires that perioperative care details are well-documented and followed by the physician's team. Importantly, these standardized processes will also enable aggregate research on outcomes.

Clinical pathways, a sequence of orders and therapies describing the routine care of the uncomplicated patient from initial patient evaluation through long-term follow-up, must be established and clearly documented.

Clinical pathways must be developed for each procedure performed by the interventionalist and hospital. Within this, surgical pathways must detail the surgical technique for each surgeon and procedure. The standardized orders referenced in the clinical pathways must be similarly detailed and adhered to.

Clinical pathways can be documented in a variety of formats, including tables, algorithms/process maps and paragraph form. While consistency for each endovascular program is encouraged, it is not mandatory.

Clinical pathways must be formally adopted and implemented prior to the ACSQ site inspection. Nurses, physician assistants, residents, applicant physicians and other applicable staff must be aware of and following them.

Four clinical pathways are mandatory:

- Perioperative care, including monitoring and airway management
- Deep vein thrombosis (DVT) management
- Management of warning signs of complications such as tachycardia and hemorrhage

Ten of the following 11 clinical pathways are also required:

- Indications
- Contraindications

- Initial patient instruction
- Patient evaluation
- Laboratory studies
- Imaging studies
- Patient education/consent
- Admission workup and evaluation
- Preoperative and postoperative nutrition regimen
- Wound care management
- Pain management

8. Vascular Nurses, Physician Extenders and Program Coordinator

Applicant utilizes designated nurse or physician extenders who are dedicated to serving vascular patients and who are involved in continuing education in the care of vascular patients.

Hospitals and surgeons must create an invasive endovascular therapies program in which the non-physician staff members can manage day-to-day aspects in compliance with the ESCOE requirements, including the provision of patient education.

Nurses and physician extenders: hospitals must have designated surgical and nonsurgical nurses as well as physician extenders who serve endovascular surgical patients. These individuals must receive the ongoing in-service education outlined in Requirement 1.

Physician extenders are defined as any healthcare provider who assists an interventionalist.

Patient education: hospitals and surgeons should have nurses and physician extenders who provide education and care to vascular patients undergoing endovascular procedures.

Designated invasive endovascular therapies area: hospitals must have a dedicated vascular floor or designated cluster/group of beds that are maintained in a consistent area of the hospital. The area must be staffed with a team of dedicated vascular nurses and physician extenders.

Endovascular program coordinator: invasive endovascular programs must have a designated vascular coordinator who supervises program development, patient and staff education, ongoing ESCOE compliance and multidisciplinary team meetings. This person serves as the liaison between the affiliated hospital and endovascular practice(s).

A licensed health care professional must occupy the endovascular coordinator position full-time if the endovascular program handles more than 150

endovascular procedures annually or part-time if 150 or less. These duties can be split between two individuals, as long as one is a licensed health care professional.

9. Long-Term Patient Follow-Up

Applicant provides documentation of a program dedicated to a goal of long-term patient follow-up of at least 75 percent for endovascular procedures at five years with a monitoring and tracking system for outcomes, and agrees to provide surgical outcomes data on all patients in a manner consistent with Health Insurance Portability and Accountability Act (HIPAA) regulations.

Hospitals and surgeons must have a comprehensive long-term patient follow-up program that consistently monitors and tracks outcomes, complications and comorbidities for all invasive endovascular therapies patients. The program must be designed with the goal of following up with 75% of all patients for five years or more after invasive endovascular therapies.

The long-term patient follow-up process must be thoroughly documented and identify which patients are included in follow-up (e.g., all patients, all operated patients or incomplete patient entry). This includes identification of the persons or entities responsible for follow-up, frequency and timing of post-discharge follow-up visits as well as formats and tools for tracking and documenting follow-up visits.

The responsible physician does not need to personally provide the follow-up. However, endovascular programs need to have mechanisms in place to follow the care if it is delivered by another/third party licensed or certified health care provider.

10. Limitations

The Applicant maintains that their facility will agree to limit endovascular procedures performed as an outpatient or 23 hours, 59 minutes stay to procedures in low risk patients (defined as patients age less than 60, a Body Mass Index (BMI) of less than 55, an American Society of Anesthesiologists (ASA) classification of less than IV (four), and no previous history of deep venous thrombosis (DVT) or pulmonary embolism (PE).

Free Standing Outpatient Programs and surgeons must have limitations on the outpatient nature of invasive endovascular procedures. The goal is to protect patients and provide a safe environment for procedures to be undertaken in a setting that provides optimal quality care.

6.4 **Full Approval**

Prior to applying for Full Approval status, the Center must first have been granted Conditional Status. While Conditional Status is based on the adequacy of resources, Full Approval is based on the achievement of acceptable outcomes.

ACSQ anticipates developing additional guidelines and criteria for Full Approval based on outcomes data reported by program participants and by other databases. Future applications for Full Approval as well as renewal applications will be required to meet any outcomes data requirements and guidelines which may be in place at the time of application or renewal.

The application for Full Approval as an Accreditation Council of Surgical Quality (ACSQ) Center of Excellence® requests:

Information to assure that the requirements for Conditional Status remains satisfied. Information regarding the patient populations, the operations performed, and their outcomes.

Full Approval requires a site inspection. The process is initiated once the application for Full Approval has been received by ACSQ. Nurses trained and experienced in invasive endovascular therapies who are full-time employees of ACSQ conduct the inspections following a prescribed protocol that includes:

- A careful review of the facilities.
- Interviews with the staff and key leaders of the facility.
- Random chart reviews.
- The purpose of the site inspection is to gather data, not to make judgments. The information collected during the site inspection is then submitted to Accreditation Council of Surgical Quality (ACSQ) for review with the Full Approval application. If the guidelines for Full Approval have been met, approval is granted for a term of three years.

Programs that fail to maintain standards may be placed on Probationary Status. If the deficits are not corrected or if there are egregious findings, the ACSQ may also recommend to the ACSQ review committee that the designation as a Endovascular Surgery Center of Excellence® be revoked.

If a program disagrees with the decisions of the ACSQ, it can appeal the matter to the Board of Directors.

The Full Approval application process to become an ACSQ Center of Excellence involves the following steps:

1. The center and its surgeons continue to meet the criteria required for Conditional

Status and fully comply with the 9 requirements for Conditional Status.

2. Any deficiencies noted during the Conditional Status review have been corrected.
3. A complete and accurate description of changes in the institution or the staff (since the Conditional Status application) has been submitted to the ACSQ.
4. A list of the academic activities of the surgeons including grants obtained, papers published, presentations, participation in courses, etc. has been provided.
5. The surgeon must be, or must have been, board certified by either the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPSC).
6. Outcomes data for endovascular surgery are reported in accordance with HIPAA regulations.

6.5 **Process - Conditional Status**

The ACSQ Invasive endovascular therapies Centers of Excellence® program is a rigorous process designed to adequately determine those hospitals, surgeons and surgery centers that meet the established program requirements for providing excellent endovascular surgical care. The charts below detail each step of the application process to become an Endovascular Surgery Center of Excellence®.

6.6 **Process - Full Approval**

Prior to applying for Full Approval status, the Center must first have been granted Conditional Status. While Conditional Status is based on the adequacy of resources, Full Approval is based on the achievement of acceptable outcomes.

ACSQ anticipates developing additional guidelines and criteria for Full Approval as a freestanding outpatient Endovascular Surgery Center of Excellence® (ESCOE) based on outcomes data reported by program participants and by other databases. Future applications for Full Approval as well as renewal applications will be required to meet any outcomes data requirements and guidelines which may be in place at the time of application or renewal.

The application for Full Approval as a freestanding ACSQ ESCOE requests:

Information to assure that the requirements for Conditional Status remain satisfied.

Information regarding the patient populations, the operations performed, and their outcomes.

Full Approval requires a site inspection. The process is initiated once the application for

Full Approval has been received. Nurses or allied health care professionals trained and experienced in endovascular surgery who are employees of ACSQ conduct the inspections following a prescribed protocol that includes:

A careful review of the facilities.

Interviews with the staff and key leaders of the facility.

Random chart reviews.

The purpose of the site inspection is to gather data, not to make judgments. The information collected during the site inspection is then submitted to the ACSQ Review Committee (ARC) for review with the Full Approval application. If the guidelines for Full Approval have been met, approval is granted for a term of three years.

Programs that fail to maintain standards may be placed on Probationary Status. If the deficits are not corrected or if there are egregious findings, the ACSQ may also recommend that the designation as a freestanding ESCOE be revoked.

If a program disagrees with the decisions of the ACSQ, it can appeal the matter to the Board of Directors.

The Full Approval application process to become a freestanding ACSQ ESCOE involves the following steps:

1. The center and its surgeons continue to meet the criteria required for Conditional Status and fully comply with the 13 requirements for Conditional Status.
2. Any deficiencies noted during the Conditional Status review have been corrected.
3. A complete and accurate description of changes in the institution or the staff (since the Conditional Status application) has been submitted to the ACSQ.
4. A list of the academic activities of the surgeons including grants obtained, papers published, presentations, participation in courses, etc. has been provided.
5. The surgeon must be, or must have been, board certified by either the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPS).
6. Outcomes data for bariatric surgery are reported in an anonymous fashion in accordance with HIPAA regulations. Outcomes data must include a list of all bariatric surgical operations performed within the previous 12-month period including the following information (partial list):

- Age

- Gender
- Weight
- Height
- BMI
- Co-morbidities
- Procedure
- Length of Stay

Complications including mortality, re-admissions within 30 days of discharge, re-operations within 30 days after the initial operation

6.7 **Site Inspection**

The purpose of the site inspection is to verify that the information submitted in an application is accurate, and to substantiate and confirm that the requirements for Full Approval as a Bariatric Surgery Center of Excellence have been met. At the time the site inspection is scheduled, a detailed instruction letter and checklist will be sent to help with preparation for the inspection. The checklist will give details regarding the staff members and materials that will need to be assembled for the site inspectors.

Everything the site inspectors need to see will be included on the checklist; this is not a surprise inspection. Gathering the necessary materials will facilitate a smoother inspection. Failure to provide the necessary materials could result in the termination of the inspection. For most Centers, site inspections will take approximately one day. However, if a Center has multiple surgeons and practices as co-applicants, it may take longer.

The site inspectors will not provide a determination or give advice during the inspection.

The information collected by the site inspectors is submitted to the Bariatric Surgery Review Committee (BACSQ) for evaluation. Based upon the site inspection findings and the information provided in the application, the BACSQ will make recommendations to the American Society for Metabolic and Bariatric Surgery (ASMBS). The ASMBS will announce those Centers which it recognizes as Bariatric Surgery Centers of Excellence. A letter will be mailed informing Centers of the results.

From the date of the site inspection until the center is notified, the process normally takes approximately 90 days. If issues arise during the site inspection that require additional information to be obtained, this could lengthen the review process.

6.8 **Fee Structure**

ACSQ values our participants' commitment to the ACSQ Endovascular Surgery Center of Excellence® (ASCOE) program. We listen to their feedback and are constantly improving our program based on this input. As a result, ACSQ has simplified our fee structure and significantly reduced the upfront costs of participation in the ESCOE

program.

International Practice

Initial Application Fee: \$8,500

Facilities pay an initial application fee of \$6,500, which includes one year of participation

Annual Participation Fee: \$3,975

Surgeons

Initial Application Fee: \$500

Surgeons pay an initial application fee of \$500

Annual ESCOE Participation Fee: \$500

Practices

The surgical practice linked with the surgeon(s) and facility applying for designation does not pay any additional or separate fees.

Site Inspection

Site Inspection Fee: \$1,850

The site inspection fee is invoiced when the site inspection is scheduled. Additional site inspection fees will be billed at the completion of the site inspection if the inspection requires more than one site inspector and/or more than one site inspection day.

Methods of Payment

Fees must be paid by check or credit card. A Credit Card Payment Form (and a W-9 Form if needed) can be requested by contacting ACSQ Support at +1.866.790.4772 (US and Canada) or support@acsq.org. All payments should include your ACSQ ID number, name of the facility or surgeon, and applicable invoice number.

Credit card: Payments are not accepted over the phone and require a Credit Card Payment Form with an authorized signature (electronic signatures are not accepted). Forms should be faxed to the attention of Accounting at 1.617.869.4141.

Check: Funds must be drawn from a US account. ACSQ does not accept checks drawn on a foreign account.

Fees paid by check should be made payable to Accreditation Council for Surgical Quality and mailed to:

CHAPTER 7 - ACSQ POLICY ON CONFLICTS OF INTEREST AND CONFIDENTIALITY

7.1 **Purpose**

ACSQ has adopted this policy as part of its continuous efforts to improve the organization's reputation for accurate and unbiased work to optimize patient and donor care and safety. This expanded conflicts of interest and confidentiality policy reflects the core values that have guided this organization since its inception — the pursuit of excellence, focus on the patient and donor, integrity, transparency, consensus building and innovation. By putting this policy into place, ACSQ continues to integrate the core values into its daily activities, helping to ensure that its decision-making processes are beyond reproach.

This policy is not intended to discourage participation in ACSQ activities. Rather, by requiring those involved in the decision-making process to disclose actual and apparent conflicts of interest, the policy encourages transparency and safeguards the integrity of ACSQ's mission.

7.2 **Responsibility**

This policy shall be maintained by the Executive Office and updated with the support of staff counsel, as appropriate

7.3 **Policy Statement**

When making recommendations and decisions on behalf of ACSQ, board members, committee members¹, volunteer assessors and staff may not use their respective positions, information they possess about ACSQ or the property of ACSQ, in a manner that allows them to realize a monetary or other material benefit for themselves or for their spouses, partners, minor children or those with whom their income is directly shared. Accordingly, no such individual may use his or her position at ACSQ for personal gain or to benefit another at the expense of ACSQ, its mission or its reputation.

Board members, who hold positions of authority that extend to committee appointments, must be particularly sensitive to, and avoid to the extent possible, any discussions with committee chairs or members that might be perceived as exerting influence relating to issues outside the scope of official board business.

Board members, committee members, volunteer assessors and staff of ACSQ must protect the confidential information of ACSQ and must not use such information for their personal benefit or to the detriment of ACSQ.

7.4 **Definitions**

For purposes of this policy and the processes and procedures that flow from it, the

following definitions shall apply:

Actual Conflict of Interest: An actual conflict of interest arises when an individual is in a position that requires the exercise of judgment on behalf of ACSQ and the individual also has financial, professional or personal interests (either the individual's own or an interest that is attributed to the individual by virtue of interests held by a spouse, partner, minor children or someone with whom income is directly shared) of the sort that is likely to, or does directly, interfere with the exercise of the individual's judgment on behalf of ACSQ.

Apparent Conflict of Interest: The appearance of a conflict of interest is present if: there is a potential for the financial, professional or personal interests of an individual (either the individual's own or an interest that is attributed to the individual by virtue of interests held by a spouse, partner, minor children or someone with whom income is directly shared) to be at odds with the individual's obligation to ACSQ and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the individual's ability to act in ACSQ's best interests and not be compromised by that individual's financial, professional or personal interests.

Confidential Information: Confidential information includes, but is not limited to results of intermediate votes; personnel issues; information that is proprietary to, or the intellectual property of, ACSQ; unpublished data and manuscripts; draft standards and policies; deliberations relating to variance requests; and other information that has not been authorized for disclosure, has not become public and that is obtained through an individual's relationship with ACSQ.

Disclosure Statements: A key element in avoiding conflicts of interest is to ensure that those serving ACSQ provide full disclosure of any actual or apparent conflicts of interest. Accordingly, ACSQ has developed a disclosure form, which is to be completed annually and updated whenever necessary to disclose new conflicts by board members, those appointed to serve on committees and all staff. Volunteer assessors are required to complete and keep current a separate form developed by the Accreditation Department.

Financial Interest: Financial interests are direct financial holdings (exclusive of mutual funds) valued at \$15,000.00 or greater in any medical and biomedical companies, including holdings of companies whose activities are addressed in any of ACSQ's standards (e.g., medical device companies, information technology companies that produce medical software) that are held by any of the following individuals:

- board members,
- committee members (including representatives),
- volunteer assessors,
- staff,
- or the spouse, partner, minor children, or someone with whom income is directly shared of any of the individuals listed above

7.5 **Required Disclosures**

- 7.5.1 The disclosures required by this policy shall be made annually and updated as necessary as a condition of appointment to the board or a committee, serving as a volunteer assessor or of employment.
- 7.5.2 The Executive Office and the Human Resources department as set forth in Section 4.0 below, shall ensure that conflicts of interest (e.g., grants or contract support, consultancies, board positions) of board members, committee members (including representatives) and staff that present an actual or apparent conflict of interest are disclosed annually in writing and updated whenever necessary to disclose new conflicts. In addition, any changes in such conflicts shall be reflected on disclosure forms provided at every board and committee meeting.

7.6 **Board Member Disclosure of Conflicts**

- 7.6.1 At the beginning of every board meeting, the president shall discuss this policy and obtain acknowledgment from all participants that the policy is understood. This acknowledgment shall be documented in the minutes of the meeting.
- 7.6.2 The Conflicts of Interest Disclosure Form shall be completed at every board meeting by each member who has new conflicts to disclose.
- 7.6.3 The Executive Office shall have processes and procedures for maintaining the completed disclosure forms.
- 7.6.4 The disclosures shall be made available to all present at the meeting.
- 7.6.5 The ACSQ president may determine whether conflicted individuals are to be precluded from discussing and/or voting on particular issues consistent with 6.0 of this policy

7.7 **Committee Member Disclosure of Conflicts**

- 7.7.1 This policy shall apply to all ACSQ committees, work groups and to interorganizational task forces for which ACSQ is the lead organization.
- 7.7.2 At the beginning of every committee meeting, the chair shall discuss this conflicts of interest policy and obtain acknowledgement from all participants that the policy is understood. This acknowledgement shall be documented in the notes of the meeting.
- 7.7.3 The Conflicts of Interest Disclosure Form shall be completed at every committee meeting by each member who has new conflicts to disclose.
- 7.7.4 The Executive Office shall have processes and procedures for maintaining the completed disclosure forms.
- 7.7.5 The disclosures shall be made available to all present at the meeting.
- 7.7.6 The chair may determine whether conflicted individuals are to be precluded from discussing and/or voting on particular issues consistent with 6.0 of this policy.

7.8 **Staff Disclosure of Conflicts**

- 7.8.1 The Human Resources department shall ensure that all staff complete the Conflicts of Interest Disclosure Form on an annual basis and update whenever necessary to disclose new conflicts.
- 7.8.2 The Conflicts of Interest Disclosure Form shall be completed at every board and committee meeting by each staff member in attendance at the meeting who has new conflicts to disclose.
- 7.8.3 The Executive Office shall have processes and procedures for maintaining the completed disclosure forms.
- 7.8.4 Disclosures made by staff attending a board or committee meeting shall be made available to all present at the meeting.
- 7.8.5 The president or committee chair, as appropriate, may determine whether conflicted individuals are to be precluded from discussing particular issues.

7.9 **Volunteer Assessor Disclosure**

- 7.9.1 The Accreditation Department shall have processes and procedures for timely disclosure of volunteer assessor conflicts of interest including a disclosure for each assessment to which an assessor is assigned.
- 7.9.2 The Accreditation Department shall have processes and procedures for maintaining completed disclosure forms.

7.10 **Effect of Disclosure**

- 7.10.1 An individual having a conflict of interest on a particular subject shall not vote on that issue.
- 7.10.2 Once a conflict has been disclosed, the president or the committee chair, as applicable, on his or her own initiative or at the request of a board or committee member, shall have the authority to require that the conflicted individual be precluded from discussing the particular issue. Where the conflict is so pervasive that it interferes with the individual's ability to serve the board or committee, the president or the committee chair, as applicable, may ask the conflicted individual to discontinue the ACSQ activity resulting in the conflict.

7.11 **Whistleblower Policies**

Board and committee members shall be entitled to the protections of the ACSQ Board and Committee Member Whistleblower Policy. Staff shall be entitled to the protections of the ACSQ Staff Whistleblower Policy.

7.12 **Recordkeeping for Board and Committee Votes**

All votes shall be recorded and all abstentions shall be recorded by name (e.g., the vote passed 7 to 5; Jane Smith abstained from discussion and Jane Smith and Joe Jones abstained from voting) in the meeting summary, notes or minutes. Agreement by consensus shall be acceptable, provided that any abstentions shall be recorded.

7.13 **Protection of Confidential Information**

7.13.1 Those serving ACSQ shall be responsible for making sure that confidential information is not disclosed to any unauthorized recipient, whether deliberately or through carelessness. Materials that contain confidential information shall be stored securely and shared only with those persons having a need to know the same. Care shall be taken to avoid inadvertent disclosure when discussing confidential information in public places and when corresponding through electronic media such as electronic mail, telephone voice mail, fax or videoconferences.

7.13.2 The president or committee chair, as applicable, shall be responsible for communicating to those covered by this policy what information should remain confidential and what information may be publicly disclosed.

7.13.3 Reports from committee or task force representatives to their organizations shall be made in writing and approved by the appropriate committee chair before being disseminated.

CHAPTER 8 - ACSQ CODE OF ETHICS AND BYLAWS

4.1 ACSQ Code of Ethics

ACSQ is a professional organization dedicated to leadership, education, service and professional integrity in the practice of blood procurement, transfusion therapy and all fields related to Transfusion Medicine. This role mandates ethical conduct. Accordingly, all ACSQ individual and institutional members hereby pledge to adhere to the following canons:

- I. Provide and promote the highest quality of service and care to patients in accordance with current scientific knowledge and established standards for practice.
- II. Cooperate with other organizations engaged in the various aspects of Transfusion Medicine when services or expertise are requested to assist in meeting the critical needs of individual patients, institutions or communities when available talents or services are requested to benefit critical needs of patients.
- III. Develop and/or support policies that prevent or eliminate the exploitation of donors and patients and oppose those measures that may adversely affect their health.
- IV. Direct efforts toward ensuring the distribution of blood, blood components and plasma derivative, without regard to race, religion, sex or creed, in a quantity that is responsive to individual, institutional and community need.
- V. Observe the confidentiality that attaches to communications, laboratory test results and other health data relating to donors or recipients, releasing such information only with requisite consent, or when required by legal compulsion or public safety.
- VI. Institutional and individual members agree to abide by the principles of fair, just, equitable and legal standards of behavior in all relations with the patients and donors that they serve, other members, the Association and members of the medical community at large.

CHAPTER 9 - ACSQ BYLAWS

1.1 **Name**

The name of the corporation is American Association of Blood Banks, an Illinois not-for-profit corporation doing business as ACSQ.

1.2 **Purposes**

ACSQ is an association of blood banks, including hospital and community blood centers, transfusion, transplantation services, and molecular testing facilities, and individuals involved in activities related to transfusion and transplantation medicine, cellular therapies, and molecular testing. ACSQ supports high standards of medical, technical and administrative performance, scientific investigation, clinical application and education to optimize patient and donor care and safety. It is dedicated to encouraging the voluntary donation of blood and other tissues and organs through education, public information and research.

ACSQ provides leadership in blood banking, tissue banking, transfusion medicine and tissue transplantation, cellular therapies, and molecular testing by:

- 1.2.1 Educating members, affiliates, physicians, other health care providers, donors, patients, policy makers and the public.
- 1.2.2 Providing a forum for professionals to exchange information and ideas.
- 1.2.3 Improving the quality and efficacy of transfusion, transplantation, cellular therapies, and molecular testing practices by establishing and promulgating standards.
- 1.2.4 Assisting our members and affiliates in ensuring a safe and adequate supply of blood and transplantable tissue.
- 1.2.5 Assisting our members and affiliates in effectively and efficiently implementing technological advances.
- 1.2.6 Promoting scientific research.

1.3 **Offices**

1.3.1 Principal Office

The principal office of ACSQ shall be the National Office and the location of the National Office may be at any place where ACSQ is qualified to operate.

1.3.2 Other Offices

District or branch offices may be established by the Board of Directors at any place or places where ACSQ is qualified to operate.

1.4 **Membership and Affiliation**

1.4.1 Classes of Membership and Affiliation

- A. There shall be separate classes of membership and affiliation as set forth in this chapter.
- B. Any member or affiliate of any class making an annual monetary contribution which is equal to or exceeding the amount as determined by the Board of Directors will be recognized as a Sustaining Member or Affiliate for that year.

1.4.2 General Requirements

- A. Membership or affiliation in each class shall be determined by the Board of Directors upon submission of a completed official membership or affiliation application.
- B. No member or affiliate of any class, by virtue of that membership or affiliation, acquires any pecuniary or proprietary interest in ACSQ's property or other assets and no member or affiliate shall be entitled to receive any part of ACSQ's earnings or assets by such membership or affiliation.
- C. Institutional Members, International Institutional Members, and Affiliates must operate as ethical and otherwise acceptable organizations whose policies are executed with medical direction which is in accordance with generally accepted ethics and standards of the medical profession and ACSQ.
- D. Institutional Members and International Institutional Members must maintain accreditation through ACSQ's Accreditation Program.

1.4.3 Institutional Membership

- A. Facilities that collect, process, test or administer blood or provide cellular therapies or molecular testing services shall be eligible to become Institutional Members.
- B. Each Institutional Member shall have one vote in any regular or special meeting of ACSQ and in any election of officers, district directors or at-large directors.

1.4.4 Affiliates

- A. Any organization, facility or professional group in the health profession which does not qualify for Institutional Membership or is not licensed and/or registered by the Food and Drug Administration, but is interested in

transfusion and transplantation medicine, cellular therapies or molecular testing, is eligible to be an Affiliate if it meets the requirements of 2A-C of this chapter.

- B. An Affiliate shall have no vote in any election of officers or directors, nor in any regular or special meeting of ACSQ.
- C. Facilities that are licensed and/or registered by the Food and Drug Administration are ineligible to become Affiliates.

1.4.5 International Institutional Membership

- A. Any organization, facility or professional group in the health care profession not located in the United States of America or its territories may apply for International Institutional Membership.
- B. International Institutional Members must be accredited under ACSQ's International Accreditation Program.
- C. An International Institutional Member shall have no vote in any election of officers or directors, nor in any regular or special meeting of ACSQ.

1.4.6 Individual Membership

- A. Active Membership. Any individual who is currently involved in activities related to transfusion and transplantation medicine, cellular therapies or molecular testing may be an Active Member.
- B. Honorary Membership. The Board of Directors may elect to grant Honorary Membership to any person who, in its opinion, has made an outstanding contribution toward the purposes of ACSQ.
- C. Emeritus Membership. Emeritus Membership may be granted by the Board to those who have been active members of ACSQ for ten consecutive years prior to retirement, providing said members make application for such status.
- D. Each Individual Member shall have one vote in any election of officers, district or at-large directors and in any regular or special meeting of ACSQ.

1.5 **Meeting of Members**

1.5.1 Regular Annual Meeting

ACSQ shall hold a regular administrative, scientific, educational and business meeting at least once each calendar year, at a time and place designated by the Board of Directors. Notice of regular annual meetings shall be given in an official publication of ACSQ at least 45 days prior to the meeting.

1.5.2 Special Meetings

Special meetings shall be called by the president on request of the Board or on petition of 20 percent of each of the Institutional Members and of the Individual Members filed with the Secretary. All special meetings shall be held at such

time and place as are designated by the Board. Notice of each special meeting shall be given in writing, and shall state its time, place and purpose, and a copy thereof shall be sent by mail or electronic means to each voting member at the address which appears in the records of ACSQ at least 30 days prior to the time of such meeting. No business shall be transacted at a special meeting other than as stated in the call thereof.

1.5.3 Quorum

A quorum shall consist of those Individual Members and those voting representatives of Institutional Members present at a regular or special meeting whose credentials have been accepted in accordance with provisions in Section 4 of this chapter.

1.5.4 Voting

For purposes of exercising its right to vote, each Institutional Member in good standing shall be officially represented by a responsible person, selected by the institution, who may vote on its behalf. All voting representatives of Institutional Members shall present credentials and be registered with the Secretary before the regular or special meeting. Individual members shall be members in good standing at the time of the regular or special meeting. No person may vote on behalf of more than one Institutional Member and himself or herself as an Individual Member in any regular or special meeting.

1.6 **Board of Directors**

1.6.1 Qualifications

Only active Individual Members may be elected to the Board of Directors.

1.6.2 Structure

The members of the Board of Directors, hereinafter referred to as the "Board," shall consist of the president, vice president, secretary/treasurer, president-elect, immediate past president, one director from each of the geographic districts defined below, four at-large directors elected from among the individual members, up to two additional directors appointed for relevant expertise by the Board of Directors and one director from each eligible Section of Individual Membership as provided in Chapter X, Section 1. The CEO shall serve as a director, ex officio, but shall not vote. There shall be no fewer than five physicians and no fewer than five non-physicians on the Board of Directors at any time. There shall be no fewer than five members of the Board who are affiliated with an ACSQ institutional member. For purposes of these requirements all directors and officers other than the CEO shall be considered. District and at-large directors shall be elected for two-year terms. Appointed directors shall serve for one-year terms. Terms for district and at-large directors

shall be staggered to provide for elections of one half of the directors each year. For purposes of a transition to this composition no director shall be removed from office until completion of his or her term.

Except with respect to the CEO serving as a director ex-officio, no individual shall serve for more than five years consecutively in any one or more director positions.

1.6.3 Duties and Responsibilities

The Board shall formulate policy for ACSQ and, subject to the Articles of Incorporation and these Bylaws, the Board is expressly empowered to receive, hold and dispose of property; to pass on questions of membership; to call meetings of ACSQ; to fix membership fees; to maintain liaison with responsible ethical organizations; to establish committees and delegate powers and duties to them (except as otherwise specified in these Bylaws); and to administer and conduct other activities of ACSQ not expressly reserved to the Membership.

1.6.4 Executive Committee of the Board of Directors

There shall be an Executive Committee of the Board comprised of the officers as defined in Chapter VII, Section 1, and the CEO. The Executive Committee shall conduct all necessary business of ACSQ in the interim between the sessions of the Board, and shall report the results of its meetings, deliberations, and other actions to the Board in a timely manner.

1.6.5 Records

The Board shall keep a complete record of its meetings and actions and shall submit reports of its trusteeship, including a financial report, for approval at the next annual or special meeting of ACSQ.

1.6.6 Nominations and Elections

The president shall appoint a Nominating Committee in accordance with the Article IX, Section 5. Nominations may also be made by the written petition of at least 20 members entitled to vote on the office, submitted at least 60 days before the annual business meeting. No nominations will be accepted from the floor at the annual business meeting.

Elections shall be conducted by mail or electronic ballot sent with the names of all nominees at least 45 days before the annual business meeting. Mail and electronic ballots must be received at the National Office at least 15 days before the annual business meeting, where the results of elections will be announced. Notwithstanding the foregoing, if there is only one nominee for each elected position, the Board of Directors may determine to hold the election at the annual business meeting rather than by mail or electronic ballot. In such event, election

shall be by oral vote of those eligible members present at the annual business meeting and entitled to vote in accordance with these Bylaws. Notice of the decision to act by oral vote shall be provided to all members immediately following the determination that there is no position available for which there is more than one candidate.

The Individual voting membership and the Institutional voting membership shall elect the officers, district and at-large directors. For purposes of exercising its right to vote, each Institutional Member in good standing shall be officially represented by a responsible person, selected by the institution, who may vote on its behalf. All voting representatives of Institutional Members shall present credentials and be registered with the Secretary before the election. Individual members shall be members in good standing at the time of the election. No person may vote on behalf of more than one Institutional Member and himself or herself as an Individual Member in any election.

1.6.7 Meetings

As soon as it is practical, and within five days following the annual business meeting of ACSQ, the newly constituted Board shall hold a regular meeting to transact any necessary business. The Board shall meet thereafter at such time and place as its members shall determine, provided that it shall always meet at the annual meeting of ACSQ. A special meeting of the Board shall be held whenever called by the president or by a majority of the members of the Board.

1.6.8 Notice of Meetings

Notice of all meetings of the Board shall be sent by mail or electronic means to each member of the Board at his or her last known address at least 15 days prior to the time of each meeting. Notice may be waived by any member of the Board before, at, or after any meeting.

1.6.9 Vacancies

Should a district director move from the district from which he or she was elected to represent, that district director shall be entitled to complete his or her term as a director representing that district. Should any director fail or be unable to fulfill his or her obligation as a director, the directorship shall be declared vacant by the Board at its next regular meeting. The remaining members of the Board of Directors, by majority vote, may appoint an individual who meets all requirements for service to complete the unexpired term of his or her predecessor in office. The remaining members of the Board may alternatively elect to allow the position to be filled by election by the voting membership in accordance with Article VI, Section 6. The elected individual will complete the unexpired term of his or her predecessor in office.

1.6.10 Quorum

A majority of Board members shall constitute a quorum for the transaction of business. Except in circumstances as specified in Sturgis Standard Code of Parliamentary Procedure, latest revision, the majority vote shall prevail.

1.6.11 Taking Office

Individuals elected to serve as members of the Board shall assume office at the beginning of the first meeting of the Board held after their election.

1.6.12 Compensation of Officers

No officer or director shall receive any pecuniary profit from his or her activities in ACSQ. Notwithstanding the foregoing, the CEO shall be entitled to receive such compensation as is awarded for performance of responsibilities related to service as the Chief Executive Officer.

1.7 **Officers**

1.7.1 Officers

The officers of ACSQ shall consist of the president, vice president, secretary/treasurer, president-elect, and immediate past president.

1.7.2 Terms

The terms of office for the vice president and the secretary/treasurer shall be one year. No individual shall serve more than three terms in any one such office. One individual shall be elected each year to become the president of ACSQ. The individual shall serve three consecutive one year terms. The initial term shall be as president-elect, the second shall be as president and the third shall be as immediate past president.

1.7.3 Duties

The president shall preside at the annual and special meetings of ACSQ. The president shall be the chairman of the Board and preside at its meetings, and shall be an ex-officio member of all committees except the Nominating Committee. The president shall appoint members to all special and standing committees, with the approval of the Board. The president-elect shall be an ex-officio member of all committees except the Nominating Committee. The president elect shall have such duties as are delegated by the president in the president's absence, and shall succeed to the office of president of the Board, shall assume the duties of the president as defined in Sections 1 and 2, of this chapter.

The vice president shall have such duties as are delegated by the Board. The

secretary/treasurer shall be responsible for the minutes of the annual and special meetings of ACSQ and of meetings of the Board. The secretary/treasurer shall sign all membership certificates and such other papers pertaining to ACSQ as he or she may be authorized to sign by the Board. The secretary/treasurer shall be responsible for serving all required notices and handle the dissemination of information to the membership. The secretary/treasurer shall be responsible for all funds and securities of ACSQ and shall ensure that all such funds and securities in the name of ACSQ or American Association of Blood Banks are in a depository or depositories in accordance with policies approved by the Board. The secretary/treasurer shall ensure that the preparation of the checks made in payment of ACSQ obligations is in accordance with policies approved by the Board. The secretary/treasurer shall furnish surety bond, shall make such reports as are required by the Board, and in general, shall perform all duties incident to the office of secretary/treasurer, and such other duties as may be assigned by the Board. The books of ACSQ shall be audited yearly by a certified public accountant.

1.7.4 Vacancies

If the office of president becomes vacant, the president-elect shall succeed and serve as president for the unexpired portion of the one-year term. In the succeeding year, the president-elect shall serve the term for which he or she was elected to be president, and the office of immediate past-president shall be vacant.

If the office of president-elect becomes vacant, it shall remain vacant for the unexpired portion of the one-year term. If the office becomes vacant for any reason other than that the president-elect succeeded to fill the unexpired portion of the president's term, then at the next annual meeting of ACSQ, a person shall be elected to serve two one-year terms, the first term as president and the second term as immediate past president.

If the office of immediate past president becomes vacant, it shall remain vacant for the unexpired portion of the one-year term.

If any other office becomes vacant, the remaining members of the Board may appoint a director to serve the unexpired portion of the term.

1.7.5 Management

Management of the activities of ACSQ shall be under the direction of a chief executive officer (CEO). The CEO may sign routine documents and instruments necessary to the transaction of the business of ACSQ, and other documents and instruments as authorized by the Board.

The CEO shall be appointed by the president with the approval of the Board. The CEO shall implement the policies of ACSQ as determined by the Board.

The CEO shall report to the president and be responsible to the Board. Other personnel required for specific activities of ACSQ shall be under the direction of and responsible to the CEO.

1.8 **Committees**

1.8.1 Standing Committees

The Standing Committees of ACSQ shall be as follows:

Audit
Bylaws
Ethics
Finance
Human Resources
Membership

1.8.2 Special Committees

Special committees may be created by the Board as provided in Chapter VI, Section 3, in order to further the interests of ACSQ.

1.8.3 Appointment

The president of ACSQ shall appoint members to all special and standing committees, with the approval of the Board, for such terms as the Board may establish. The Board may also approve appointments to committees made by the president-elect where the terms of such appointments are effective at the Annual Meeting at which the president-elect assumes the office of president. No committee member shall serve on any committee for more than 6 consecutive years, except that such member may serve as the chairman of such committee for no more than three additional years.

The Board may provide for the staggering of terms and establish policy for reappointment, subject to the limitations of these Bylaws.

1.8.4 Duties and Responsibilities

Committees shall have duties and responsibilities as the Board may assign, except as these Bylaws may otherwise specify. All committees shall report to the Board at such times and in such manner as the Board may require, and the Board may establish councils for this purpose.

1.8.5 Nominating Committee

The president, with the approval of the Board, shall appoint a Nominating Committee, to be submitted to the membership, of seven persons, one from each

of the 6 districts and a chairperson from among the entire membership, to prepare nominations for the officers, district directors and at-large directors of ACSQ. No current member of the Board shall be eligible for appointment to the Nominating Committee.

1.9 **Sections of Individual Members**

1.9.1 Formation

On the written petition of at least 15 percent of each of the Individual voting membership and the Institutional voting membership of ACSQ, the Board may establish a Section of Individual Members. No such Section may be established without defined duties to be performed and objectives to be achieved.

1.9.2 Board Representation

Each section will establish the procedures, guidelines and qualifications, subject to Board approval, for representation on the Board by a director as provided in Chapter VI, Section 2.

1.9.3 Coordinating Committees

Each section of Individual Members shall establish a Coordinating Committee through a mechanism determined by the membership of that Section. In order to achieve their objectives, the Coordinating Committees may establish task forces to carry out specifically assigned duties. Such task forces shall be responsible directly to the Board through the Coordinating Committee. The Sections of Individual Members shall not duplicate activities assigned to committees or councils established by the Board.

1.10 **Termination of Membership**

1.10.1 Nonpayment of Dues

Any member shall be considered delinquent after failure to pay dues 60 days after billing, and he or she shall be so notified by the treasurer. Members in arrears for 90 days shall be dropped automatically from the rolls for nonpayment of dues. Within one year after loss of membership for nonpayment, a member may be reinstated upon payment of all dues current and in arrears.

1.10.2 Suspension or Expulsion

A. Members.

The Board shall have the power to suspend or expel a member for noncompliance with the Articles of Incorporation, the Bylaws of ACSQ, or its Code of Ethics, or for any cause which in the judgment of the Board

shall be deemed detrimental to the interests of ACSQ. A member shall be invited to appear before the Board or a committee thereof for a hearing only after charges have been preferred in writing and transmitted by registered mail to the accused 30 days previous to the meeting. The accused may reply in writing or in person and shall be given full opportunity for defense before the Board or a committee thereof. An expelled member shall forfeit all his rights and privileges in ACSQ, and a suspended member shall forfeit all his rights and privileges during the period of his suspension. In the event that charges are preferred against an Institutional Member, that Institutional Member shall be represented by the CEO of the institution or a responsible person duly certified in writing by the CEO of the institution as the institution's representative, empowered to act on behalf of the Institution. A two-thirds vote of the entire Board shall be required to suspend or expel a member.

B. Appointed Representatives.

The Board of Directors may remove any committee member (including section coordinating committees) or other official representative of ACSQ from his position if it considers his conduct detrimental to the policies of ACSQ or his performance of duties for ACSQ is unsatisfactory. A two-thirds vote of the Board shall be required to remove any committee member.

C. Officers and Directors.

The Board of Directors may remove any officer or director from his elected position if the officer or director has acted contrary to the express, written policies of the Board to the detriment of ACSQ or his performance of duties on the Board has been unsatisfactory. The officer or director shall be invited to appear before the full Board for a hearing only after charges have been proffered in writing and transmitted by registered mail to the officer or director 30 days previous to the hearing. The officer or director may reply in writing, in person, or both, and shall be given full opportunity for rebuttal of the charges. A two-thirds vote of the entire Board shall be required to remove an officer or director.

1.11 **Miscellaneous**

1.11.1 Rules of Order

Sturgis Standard Code of Parliamentary Procedure, latest revision, shall govern the conduct of all meetings.

1.11.2 The Seal

The seal of ACSQ shall consist of a shield bearing the words "Vitae Custodes;" above this shield shall be a streamer with the words "American Association of Blood Banks;" and below the shield a second streamer with the words, "Founded

in Dallas, Texas, November 19, 1947."

1.12 **Amendments**

The Board is specifically empowered to amend these Bylaws provided the amendments are ratified by a two-thirds vote of the Board members present and voting, and provided further, that they are ratified by a two-thirds majority of each of the Individual voting membership and the Institutional voting membership present at the next regular annual business meeting or special meeting of ACSQ. The proposed amendments must be sent to each voting membership in writing by mail or electronic means at least 45 days before the meeting, and in compliance with Chapter V, Section 2, in the case of a special meeting. Amendments to the form thereof by the voting membership shall be permitted only if posted on a designated bulletin board, at a place convenient for all to see, 24 hours before the meeting. Approved amendments shall become effective at the close of the meeting.

1.13 **Indemnification**

In accordance with the conditions and limitations set forth herein, ACSQ shall indemnify any person named, or threatened to be named, a party to a formal court proceeding or lawsuit, whether civil or criminal, by reason of the fact that such person is or was an ACSQ employee, officer, director, committee member or other agent under its direct supervision and control and within the scope and course of such person's duties as such. Any person covered under this policy shall be indemnified in full against all costs and expenses, including attorneys' fees, judgments, fines, and amounts paid in settlement, actually and reasonably incurred by such person, in connection with the defense of such proceedings or lawsuits, to the extent such indemnification is lawfully permitted.

1.14 **Conditions and Limitations**

Any person seeking indemnification shall:

- A. notify the General Counsel of ACSQ in writing as soon as practicable after such person becomes aware that a claim has been made against him/her, but in any event, fewer than 20 days after the date such person has been served in a lawsuit. The person should promptly furnish to the General Counsel all information known to such person about the proceedings or lawsuit;
- B. agree to representation, defense and settlement by counsel selected and approved by the General Counsel;
- C. agree to repay to the ACSQ any advances already made if it is subsequently determined that a person is not entitled to indemnification pursuant to (b), and if any expenses have been paid on behalf of such person; and
- D. agree that all entitlement to indemnification shall be determined exclusively by the

provisions of this bylaw.

- E. Indemnification shall be made only upon a determination that the person seeking it, in respect to the facts underlying the proceedings or lawsuit, acted in good faith and in a manner such person reasonably believed to be in the best interests of ACSQ; that in respect to any alleged criminal conduct, such person had no reasonable cause to believe his/her conduct was unlawful; and that such person did not act with malice, dishonesty, or gross negligence.
- F. As soon as practicable after receipt of such notice, the General Counsel shall make a determination as to the provision of indemnification to the person in question.
- G. In the event that indemnification is denied, the individual so denied indemnification may appeal such determination, within 30 days, to the Board of Directors. A majority vote of the Board of Directors shall be required to obtain the indemnification so denied.
- H. In the event ACSQ pays indemnification, such information will be provided in financial statements to the voting membership of ACSQ prior to the next annual meeting.

Outside Directorships

- I. Indemnification shall not be provided to any volunteer or employee who serves as an outside director or officer of any organization or corporation for services in that organization or corporation unless a formal request for such indemnification is filed with and approved by the President or CEO upon a finding that the outside position serves an essential purpose of ACSQ. An ACSQ volunteer or employee serving as an outside director or officer of another organization at the request of the Board of Directors shall be indemnified. Any offer or indemnification shall be in accordance with the conditions and limitations of this bylaw.

CHAPTER 10 - ACSQ CODE OF ETHICS AND BYLAWS

Introduction to the ACSQ Brand ACSQ logos, trademarks, wordmarks and taglines are all part of the association's intellectual property and comprise one of its most valuable assets, the ACSQ Brand. Throughout history, the ACSQ Brand has represented the association's commitment to the highest standard of quality. In order to protect the ACSQ corporate brand identity, it is essential that all representations of the ACSQ Brand be truthful, fair, not misleading, and in compliance with these Guidelines.

a. **Intended Audience**

These ACSQ Brand Usage Guidelines are universal and apply to: ACSQ employees, ACSQ Institutional and Individual Members, Affiliates, vendors, exhibitors, advertisers and the general public. Use of ACSQ trademarks constitutes acceptance of these Guidelines.

b. **Usage of the ACSQ Brand**

Prior Written Permission Required

Written approval must be obtained from ACSQ prior to use of the ACSQ Brand. Written requests should be submitted to ACSQ either by mail to Attention: Marketing Department, 8101 Glenbrook Road, Bethesda, MD 20814, or email to marketing@acsq.org.

Please note the following rules when applying these Guidelines:

Unlicensed use of ACSQ logos is not permitted.

Only accredited ACSQ Institutional Members in good standing may use the "ACSQ Accredited" logo. Once approved, Institutional Members may use the "ACSQ Accredited" logo on letterhead, advertisements, general business correspondence and their official Web sites.

Use of ACSQ logos is not permitted on products or packaging.

ACSQ Affiliates may not use any ACSQ logos in any form or for any purpose.

While ACSQ appreciates the decision of brokers and other third-parties to use facilities accredited by ACSQ, use of ACSQ logos on Web sites or the promotional material of these third-party entities is strictly prohibited.

When using ACSQ logos, the appropriate trademark symbol and trademark acknowledgment of ACSQ ownership of the logos is required.

ACSQ logos may not be incorporated into product names, service names, domain names, trademarks, logos or company names. Logos that are confusingly similar to those of

ACSQ should not be adopted.

c. **Trademark License**

Grant of Limited License

Through its written approval to use the ACSQ Brand, ACSQ grants a limited, revocable, non-exclusive license to use certain ACSQ logos as detailed in each logo's corresponding style guide. This license cannot be sub-licensed to another third-party under any circumstances.

Termination of License

ACSQ may suspend or terminate this license at any time if, in its sole discretion, it finds use of the ACSQ logos does not conform to these Guidelines or is otherwise objectionable to ACSQ for any other reason. The most recent version of the ACSQ Brand Usage Guidelines may be found at www.acsq.org. The license to use any ACSQ logo is automatically terminated if: an institution loses its accreditation or its ACSQ member status for any reason, including failure to pay dues. In either event, the licensee must immediately stop all use of the ACSQ logos and destroy any material, goods or other documentation in its possession or control that contain the logos.

d. **Limitation of Liability**

ACSQ disclaims all liability to any licensee, their clients, customers, and any third-parties, relating to the use of ACSQ logos, or the goods or services provided by a licensee. The licensee agrees to indemnify, defend and hold ACSQ harmless from any and all costs, damages, expenses or losses of any nature (including reasonable attorney's fees) resulting from any claim arising out of licensee use of the ACSQ logos to the full extent permitted by the law. The ACSQ logos are provided AS-IS without warranty of any kind, whether express or implied, including any implied warranty of non-infringement. In no event shall ACSQ be liable for any direct or indirect damages, including, but not limited to, those for lost profits or business interruption, speculative, consequential, incidental, special, punitive or exemplary damages regardless of whether such liability is based in tort, contract or otherwise, so long as such limitations are consistent with state law. ACSQ reserves the right to modify these Guidelines from time to time in any way that best protects its interests.

e. **ACSQ Brand Style Guide**

This style guide outlines how each logo must be applied. In general, when using any ACSQ logo, the following graphic rules apply:

Always use the electronic file provided by the ACSQ Marketing Department.

PMS for coated/uncoated printing

CMYK for 4-color process printing

RGB for Web use

The ACSQ logos may not be modified in any way. Their use must be exactly as depicted in the corresponding logo's style guide, including same font size, colors, spacing and proportions.

A minimum of 1/2" white space must surround any ACSQ logo.

All ACSQ logos must be produced for optimum legibility with no distortion.

When sizing the logos, reduce or enlarge the graphic staying true to original proportions.

The logos must always be oriented in an upright manner.

Do not add or apply any graphical treatment to the logos.

Any use of the ACSQ logos except as authorized in these ACSQ Brand Usage Guidelines requires advance written permission from ACSQ. If you are interested in obtaining a license to use the logos other than as permitted in these Guidelines, contact the ACSQ Marketing Department, at +1.301.215.6498 or marketing@acsq.org.

CHAPTER 11 – CONSULTATION SERVICES

For inpatient and outpatient facilities interested in developing an endovascular surgery program, the ACSQ offers consultation services to assist program development. Only facilities without existing bariatric surgery programs are eligible for this service.

11.1 **Consultation Services**

The ACSQ will assist in identifying opportunities for:

- A. Surgeon training
- B. Proctoring
- C. Preceptoring

The ACSQ can assist in building a bariatric surgery team

The ACSQ can assist in organizing consultation with:

- A. Nursing
- B. Anesthesiology
- C. Interventionalists
- D. Other essential team members including:
 - i. Dieticians
 - ii. Social workers
 - iii. Clinical psychologists

CHAPTER 12 – REFERENCES

1. CDC. National Center of Health Statistics. In.
2. Borja-Cacho D, Parsons HM, Habermann EB, Rothenberger DA, Henderson WG, Al-Refaie WB. Assessment of ACS NSQIP's predictive ability for adverse events after major cancer surgery. *Ann Surg Oncol* 2010;17:2274-82.