INTERSOCIETAL ACCREDITATION COMMISSION

CAROTID STENTING

IAC Standards for Carotid Stenting Accreditation

Accreditation Standards

AUGUST 2025

Introduction

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

This program is designed to accredit facilities that perform stenting of the extracranial carotid artery by ensuring that the facility meets benchmarks for quality based on resources, training and outcomes. Carotid stents may be appropriately placed for many indications (See Appendix), but the most common indication, and the indication for which outcome data is most widely available, is treatment of carotid bifurcation disease secondary either to atherosclerosis, post endarterectomy restenosis or radiation induced stenosis. Therefore, the outcome benchmarks used in this program are intended to be applied only to cases treated for these indications. A facility that is able to meet the outcome benchmarks for these most common indications will most likely provide adequate outcomes for carotid stenting performed for less common indications (See Appendix).

Carotid stenting with cerebral protection was developed for endovascular revascularization of extracranial carotid disease utilizing percutaneous access. Percutaneous access is typically transfemoral but can also include transradial or other percutaneous access other than direct carotid puncture. Transcarotid revascularization (TCAR) is a hybrid procedure combining direct surgical exposure and control of the common carotid artery at the base of the neck and catheter-based, fluoroscopic image-guided intervention in the carotid artery for stent placement. There are procedural similarities as well as differences that allow for commonality with regard to procedural standards and some unique aspects that apply to each.

A carotid stenting facility consists of at least one designated fluoroscopy system, a qualified physician, a nurse and an interventional technologist. Each facility must have a Medical Director and Technical/Administrative Director. The facility must meet the organizational requirements defined in this document. There may be additional physicians, interventional technologists and other professional and/or ancillary personnel. When more than one technical member is employed, a Technical/Administrative Director is responsible for supervision of the technical staff. If stenting is performed in more than one location within one facility, the facility is encouraged to apply for all locations within that facility under the overall direction of a Medical Director(s). All operators and all cases under the direction of the Medical Director(s) must be included in the application for accreditation.

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

New or emerging technologies, protocols and other novel imaging or interventional approaches not included in guidelines published by professional societies must have supporting documentation that demonstrates adherence to manufacturer's training, safety specifications and quality control specifications as applicable. Facilities are encouraged to contact the IAC for guidance related to utilization of new technology not currently addressed in the IAC Standards.

These accreditation Standards are the minimum standards for accreditation of carotid stenting facilities. Standards are the minimum requirements to which an accredited facility is held accountable. In addition to all standards listed below, the facility, including all staff, must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

Standards that are highlighted are updates that were made as part of the August 15, 2025 revision and effective immediately.

Part A: Organization

Section 1A: Personnel and Supervision

STANDARD – Medical Director

1.1A The Medical Director must be a licensed physician.

1.1.1A Medical Director Required Training and Experience

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

1.1.1.1A board certified in his/her specialty; and

1.1.1.2A have clinical expertise in the management of extracranial carotid occlusive disease but need not personally perform cervical/extracranial carotid angioplasty and/or stenting.

1.1.2A Medical Director Responsibilities

The Medical Director is responsible for all cervical/extracranial carotid angioplasty and stenting services provided, including compliance, radiation safety, outcomes, quality control, quality of care and appropriateness of care provided. The Medical Director responsibilities include but are not limited to:

1.1.2.1A Compliance with all facility policies/procedures/protocols and will review and update all manuals periodically as necessary (minimum every three years) or as new policies are introduced. This review must be documented via signature (or initials) and date on the reviewed document or manual.

1.1.2.2A Active oversight of radiation safety within the facility as evidenced by membership on the institution's radiation safety committee or periodic review of radiation safety issues and documentation. The radiation protection program content and implementation must be reviewed at least annually.

1.1.2.3A Delegation, when appropriate, of the supervision of radiation safety standards to the Technical/Administrative Director, radiation safety officer or health physics consultant. Records of radiation safety must be kept on file in accordance with local requirements and available for inspection.

1.1.2.4A The review and oversight of the clinical practice of cervical/extracranial carotid angioplasty and stenting services.

1.1.2.5A The Medical Director must provide oversight and documentation of comprehensive Quality Improvement (QI) Program. Reference Section 1C: Quality Improvement Program.

Comment: The Medical Director may supervise the entire operation of the facility or delegate specific operations but is responsible for assuring compliance of medical and technical staff to the standards outlined in this document.

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1.1.3A Continuing Medical Education (CME) Requirements

1.1.3.1A The Medical Director must obtain at least 15 hours of Category I CME credits, relevant to cerebrovascular disease that includes but is not limited to content that is directly related to the performance of cervical/extracranial carotid angioplasty and/or stenting and/or carotid atherosclerotic disease every three years. Radiation safety training must be part of the CME and not be less than one hour of the 15 hours required. If the Medical Director performs these procedures, he/she must meet the qualifications and maintenance of qualifications of the medical staff.

Comment: If the Medical Director has successfully attained one or more of the following within the three years prior to the application date, the CME requirement will be considered fulfilled:

i. completion of an Accreditation Council for Graduate Medical Education (ACGME) approved (or similarly recognized) residency or fellowship; or

ii. attaining certification by an American Board of Medical Specialties (ABMS) recognized board.

1.1.3.2A Documentation of CME credits must be kept on file and available for inspection.

STANDARD – Medical Staff

1.2A All members of the medical staff must be licensed physicians.

1.2.1A Medical Staff Required Training and Experience

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

1.2.1.1A For percutaneous procedures, the medical staff member(s) must meet one of the published national society training standards pertaining to cervical/extracranial carotid angioplasty and stenting and be credentialed by the health care facility to perform percutaneous cervical/extracranial carotid angioplasty and stenting. The currently acceptable national society training standards are:

i. Training, Competency and Credentialing Standards for Diagnostic Cervicocerebral Angiography, Carotid Stenting and Cerebrovascular Intervention: A Joint Statement from the American Academy of Neurology, American Association of Neurological Surgeons, American Society of Interventional and Therapeutic Neuroradiology, American Society of Neuroradiology, Congress of Neurological Surgeons AANS/CNS Section, and Society of Interventional Radiology.[5]

ii. Clinical Competence Statement on Carotid Stenting: Training and Credentialing for Carotid Stenting – Multispecialty Consensus Recommendations: A Report of the SCAI/SVMB/SVS Writing Committee to Develop a Clinical Competence Statement on Carotid Interventions.[12]

iii. Qualification Requirements for Performing Neurointerventional Procedures: A Report of the Practice Guidelines Committee of the American Society of Neuroimaging and the Society of Vascular and Interventional Neurology.[11]

iv. Other national society training standards may be considered appropriate subject to review and approval by the IAC Carotid Stenting Board of Directors.

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1.2.1.2A All physicians (including the Medical Director, if applicable) performing percutaneous cervical/extracranial carotid angioplasty and stenting must be privileged by clear and concise requirements as outlined by their hospital privileging committee that include periodic review and documentation of credentialed staff.

1.2.1.3A For TCAR procedures, the medical staff member(s) must meet one of the published national society training standards pertaining to TCAR and be credentialed by the health care facility to perform TCAR. The currently acceptable national society training standards are:

i. Clinical Competence Statement of the Society for Vascular Surgery on Training and Credentialing for Transcarotid Revascularization. J Vasc Surg 2020 Sep;72(3):779-789.14

ii. Other national society training standards may be considered appropriate subject to review and approval by the IAC Carotid Stenting Board of Directors.

1.2.2A Continuing Medical Education (CME) Requirements

1.2.2.1A The medical staff members must obtain at least 20 hours of Category 1 CME credits, relevant to percutaneous therapeutic endovascular intervention and cerebrovascular disease every three years. Of these, 10 credit hours should be relevant to cervical/extracranial carotid angioplasty and stenting. Radiation safety training must be part of the CME and not be less than one hour of the 20 hours required.

Comment: If the medical staff member has successfully attained one or more of the following within the three years prior to the application date, the CME requirement will be considered fulfilled:

i. completion of an Accreditation Council for Graduate Medical Education (ACGME) approved (or similarly recognized) residency or fellowship; or

ii. certification by an American Board of Medical Specialties (ABMS) recognized board.

1.2.2.2A Documentation of CME credits must be kept on file and available for inspection.

STANDARD – Interventional Technologist Technical/Administrative Director

1.3A The Technical/Administrative Director must be either an interventional technologist or interventional nurse (1.4A) and meet the required training and experience qualifications as outlined.

1.3.1A Interventional Technologist Technical/Administrative Director Required Training and Experience

The Interventional Technologist Technical/Administrative Director must demonstrate an appropriate level of training and experience by meeting one the following criteria:

1.3.1.1A A registered radiologic technologist with the American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) with post primary certification in one of the following:

i. Cardiac-Interventional Radiography RT(CI);

ii. Vascular-Interventional Radiography RT(VI);

iii. Cardiovascular-Interventional Radiography RT(CV); or

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iv. Registered Cardiovascular Invasive Specialist (RCIS).

1.3.1.2A A registered radiologic technologist with the American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) with a minimum of five years of experience performing interventional, vascular or cardiology procedures. A letter from the Medical Director or supervising physician verifying the training, experience and competency in performance and supervision of CAS procedures is required.

Comment: In the event that the Technical Director applying under pathway 1.3.1.2A no longer works in this capacity, the newly appointed Technical Director must meet training pathway 1.3.1.1A.

1.3.2A Interventional Technologist Technical/Administrative Director Responsibilities

The Interventional Technologist Technical/Administrative Director responsibilities may include, but are not limited to:

1.3.2.1A the day-to-day operations of the facility;

1.3.2.2A the delegation, when necessary, of specific responsibilities to the technical and/or ancillary staff; and

1.3.2.3A verification of documentation of proper training and, at least annually, assessment of the competence of technical staff and/or any ancillary staff who report to the Technical/Administrative Director.

1.3.3A Continuing Education (CE) Requirements

1.3.3.1A The Interventional Technologist Technical/Administrative Director must obtain at least 15 hours of accredited CE in percutaneous interventional procedures or patient management every three years. Radiation safety training must be part of the CE and not be less than one hour of the 15 hours required.

1.3.3.2A All CE hours must be approved (i.e., Recognized Continuing Education Evaluation Mechanism (RECEEM), American Registry of Radiologic Technologists (ARRT)-Category A, American Society of Radiologic Technologists (ASRT), American Medical Association (AMA), American Nurses Credentialing Center (ANCC)-Category I).

Comment: If the Technical/Administrative Director has successfully attained an appropriate technical credential within the three years, prior to the application date, the CE requirement hours will be considered fulfilled.

1.3.3.3A Documentation of CE credits must be kept on file and available for inspection.

STANDARD – Interventional Nurse Technical/Administrative Director

1.4A The Technical/Administrative Director must be either an interventional technologist (1.3A) or interventional nurse and meet the required training and experience qualifications as outlined.

1.4.1A Interventional Nurse Technical/Administrative Director Required Training and Experience

1.4.1.1A The Interventional Nurse Technical/Administrative Director must demonstrate an appropriate level of training and experience by meeting one of the following criteria:

i. Registered Nurse (RN);

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ii. advanced health care degree or Bachelor of Science in nursing (BSN) preferred; or

iii. certification in interventional nursing specialty such as Cardiac Vascular Nursing (CVRN), Cardiac Vascular Invasive Specialist (CVIS) or Certified Radiology Nurse (CRN).

1.4.1.2A Critical care or emergency room experience is required.

1.4.1.3A At least six months of critical care or emergency room nursing is required.

1.4.1.4A Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) certification is required.

1.4.2A Interventional Nurse Technical/Administrative Director Responsibilities

The Interventional Nurse Technical/Administrative Director responsibilities may include, but are not limited to:

1.4.2.1A the day-to-day operations of the facility;

1.4.2.2A the delegation, when necessary, of specific responsibilities to the technical and/or ancillary staff; and

1.4.2.3A verification of documentation of proper training and, at least annually, assessment of the competence of technical staff and/or any ancillary staff who report to the Technical/Administrative Director.

1.4.3A Continuing Education (CE) Requirements

1.4.3.1A The interventional nursing staff must obtain at least 15 hours of accredited CE in percutaneous interventional procedures, neurologic assessment and/or patient management, every three years. Radiation safety training must be part of the CE and not be less than one hour of the 15 hours required.

1.4.3.2A All CE hours must be American Nurses Credentialing Center (ANCC) approved. At least one contact hour in moderate sedation is required annually.

Comment: If the nursing staff member has successfully attained an appropriate specialty certification (CVRN, CVIS or CRN) within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.4.3.3A Documentation of CE credits must be kept on file and available for inspection.

STANDARD – Technical Staff (Interventional Technologist[s])

1.5A Interventional technologist(s) at the facility must meet the following qualifications:

1.5.1A Interventional Technologist(s) Required Training and Experience

The interventional technologist(s) must meet one of the following criteria:

1.5.1.1A A registered radiologic technologist with the American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) with post primary certification in one of the following:

i. Cardiac-Interventional Radiography RT(CI);

ii. Vascular-Interventional Radiography RT(VI);

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iii. Cardiovascular-Interventional Radiography RT(CV); or

iv. Registered Cardiovascular Invasive Specialist (RCIS).

1.5.1.2A A registered radiologic technologist [RT(R)] with a minimum of one year of full-time equivalent experience as an interventional technologist under the direct supervision of personnel meeting pathway 1.3.1A, as indicated above. A clinical rotation in interventional, cardiology, vascular or invasive procedures as part of their educational program may be counted for up to six months of clinical experience.

1.5.2A Interventional Technologist(s) Responsibilities

The interventional technologist(s) responsibilities may include, but are not limited to:

1.5.2.1A reporting to the Technical/Administrative Director;

1.5.2.2A reviewing and/or recording pertinent patient history and supporting clinical data;

1.5.2.3A obtaining a record of anatomical, pathological and/or physiological data for interpretation by the physician;

1.5.2.4A positioning of the patient, selection of radiation exposure parameters, imaging of the patient and archiving of the images;

1.5.2.5A maintaining a high degree of awareness of all radiation and patient safety issues involved with any invasive procedure;

1.5.2.6A demonstrating a thorough understanding and working knowledge of normal and abnormal anatomy, physiology, radiation safety, interventional supplies and equipment operation;

1.5.2.7A recognizing and resolving equipment problems and discrepancies, anticipating patient needs and concerns and communicating the appropriate care needed;

1.5.2.8A using professional judgment and critical thinking when performing procedures;

1.5.2.9A scrubbing in and assisting the physician in the procedure when necessary;

1.5.2.10A circulating within the procedure room and procuring equipment needed for any given procedure; and

1.5.2.11A performing other procedures and duties, as assigned.

1.5.3A Continuing Education (CE) Requirements

1.5.3.1A The interventional technologist staff must obtain at least 15 hours of accredited CE in percutaneous interventional procedures or patient management, every three years. Radiation safety training must be part of the CE and not be less than one hour of the 15 hours required.

1.5.3.2A All CE hours must be approved CE (i.e., RECEEM, ARRT-Category A, ASRT, AMA Category I).

Comment: If the interventional technologist staff member has successfully attained an appropriate technical credential within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.5.3.3A Documentation of CE credits must be kept on file and available for inspection.

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STANDARD – Technical Staff (Interventional Nurse[s])

1.6A Interventional nurse(s) at the facility must meet the following qualifications:

1.6.1A Interventional Nurse(s) Required Training and Experience

1.6.1.1A The interventional nurse(s) must meet one of the following criteria:

i. Registered Nurse (RN);

ii. advanced health care degree or Bachelor of Science in Nursing (BSN) preferred;

OR

iii. certification in interventional nursing specialty such as Cardiac Vascular Nursing (CVRN), Cardiac Vascular Invasive Specialist (CVIS) or Certified Radiology Nurse (CRN).

1.6.1.2A Critical care or emergency room experience is required.

1.6.1.3A At least six months of critical care or emergency room nursing is required.

1.6.1.4A Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) certification is required.

1.6.2A Interventional Nurse(s) Responsibilities

The interventional nurse(s) responsibilities may include, but are not limited to:

1.6.2.1A administering and monitoring moderate sedation;

1.6.2.2A performing neurological assessment;

1.6.2.3A knowing relevant radiation safety;

1.6.2.4A monitoring and assessing clinical status of patient;

1.6.2.5A cardiovascular and hemodynamic monitoring and management; or

1.6.2.6A advising patient care team and treating patient appropriately.

1.6.3A Continuing Education (CE) Requirements

1.6.3.1A The interventional nursing staff must obtain at least 15 hours of accredited CE in percutaneous interventional procedures, neurologic assessment and/or patient management, every three years. Radiation safety training must be part of the CE and not be less than one hour of the 15 hours required.

1.6.3.2A All CE hours must be American Nurses Credentialing Center (ANCC) approved. At least one contact hour in moderate sedation is required annually.

Comment: If the nursing staff member has successfully attained an appropriate specialty certification CVRN, CVIS or CRN within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.6.3.3A Documentation of CE credits must be kept on file and available for inspection.

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STANDARD – Neurological Assessment Examiner(s)

1.7A Neurological assessment examiner(s) at the facility must meet the following qualifications:

1.7.1A Neurological Assessment Examiner(s) Required Training and Experience

The neurological assessment examiner(s) must demonstrate an appropriate level of training and experience by meeting the following criteria:

1.7.1.1A Independent neurologic assessments (to include NIHSS and mRS) must be performed by a physician, physician extender, nurses or other qualified health care professionals as allowed by state law (i.e., physician assistant (PA) or nurse practitioner (NP) with neurological expertise). The independent examiner is defined as the person performing the assessment that is not the operator or any other person listed on the procedure documentation. Optimally, these examinations are performed by a neurologist.

1.7.1.2A The National Institutes of Health Stroke Scale (NIHSS) and Modified Rankin Scale (mRS) must be performed by personnel meeting requirements in 1.7.1.1A performed by physicians that have completed formal training and demonstrated competency in performing NIH Stroke and Modified Rankin scales. All examiners must have current NIHSS and Modified Rankin certification by a nationally recognized certification organization recognized by organizations such as the National Stroke Association or the American Stroke Association.[9] Following initial certification, initial recertification is required at six months and then annually.

i. Documentation of current NIHSS and Modified Rankin certification must be kept on file and available for inspection.

STANDARD – Ancillary Personnel

1.8A The facility must ensure that adequately trained and experienced ancillary personnel are available to perform safe and effective patient care appropriate for the level of service as designated by the Medical or Technical/Administrative Director. The specific needs of a facility must be determined by an evaluation of the types and volumes of procedures as well as facility configuration.

1.8.1A Ancillary personnel may consist of, but are not limited to:

1.8.1.1A anesthesia personnel;

1.8.1.2A technical assistants;

1.8.1.3A clerical and administrative assistants;

1.8.1.4A computer support staff; or

1.8.1.5A equipment support staff (i.e., biomedical, x-ray service).

1.8.2A All ancillary personnel within the department must be supervised by the Medical Director or a qualified designee. The supervisor must document/verify proper training, at least annually and current competence of the ancillary personnel appropriate to the assigned duties.

STANDARD – Medical Physicist

1.9A A qualified medical physicist must be retained by the facility, assume the responsibilities as outlined in Standard 1.9.2A and meet the following qualifications:

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1.9.1A Medical Physicist Required Training and Experience

The medical physicist(s) must meet one of the following criteria:

1.9.1.1A Board certification by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or the Canadian College of Physics (CCPM) in diagnostic medical physics or equivalent.

1.9.1.2A Passed Part 2 of the ABR examination and completed a CAMPEP-approved residency in a medical physics discipline, including diagnostic imaging, is acceptable. As outlined above, a recognized board certification is required prior to the next accreditation cycle.

1.9.1.3A If necessary for each state, the medical physicist must be licensed or certified as a diagnostic medical physicist.

1.9.2A Medical Physicist Responsibilities

The medical physicist(s) responsibilities include, but are not limited to:

1.9.2.1A The medical physicist should regularly perform radiation measurements, dosimetric calculations, and equipment performance evaluations of fluoroscopic equipment to maintain competence in performing these activities.

1.9.2.2A The physicist should observe at least one fluoroscopically guided procedure within each accreditation modality/area annually.

1.9.2.3A Acceptance (initial) tests and annual surveys (or more frequently as governed by state and local regulations) for equipment performance evaluation, including:

i. maximum and typical radiation output measurements in at least one clinically used protocol with a common set of operator-controlled parameters (i.e., pulse rate, field-of-view, etc.);

ii. accuracy assessment of all fluoroscope reported or displayed radiation dose indices;

iii. system quality control tests ensuring proper functionality and operation of the fluoroscope for safe and effective operation; and

iv. assessment of image quality in at least one clinically used fluoroscopy mode setting and one clinically used acquisition mode setting.

1.9.2.4A Where necessary (see 3.1.1A), evaluation of the radiation shielding adequacy and integrity ensuring necessary radiation protection to individuals in all adjacent areas (only necessary at the initial survey, after any modifications to the structural shielding or replacement of the imaging equipment).

1.9.2.5A Assessment of proper functioning of collimators and tissue compensation filters.

1.9.2.6A Provide a written summary report to the Medical Director or Radiation Safety Officer and include any identified issues requiring corrective action or recommendations for improvement.

1.9.2.7A Provide written guidance for any patient and/or staff dosimetry issues.

1.9.2.8A Provide radiation training for personnel as required.

1.9.2.9A Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist in the data collection under the

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direct supervision of the medical physicist (i.e., the physicist must be on premises and immediately available). The medical physicist must review and approve all such data. The medical physicist remains personally responsible for tasks.

1.9.3A Continuing Education (CE) Requirements

1.9.3.1A The medical physicist must obtain at least 15 credit hours of CE approved by the Commission on Accreditation of Medical Physics Education Program (CAMPEP) in diagnostic imaging every three years; at least three credits of which must be directly related to fluoroscopy.

Comment: Actively participating in and fulfilling the requirements of ABR MOC meets this requirement.

Comment: If the medical physicist has successfully attained board certification within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.9.3.2A Documentation of CE credits must be kept on file and available for inspection.

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Section 2A: Facility

STANDARD – General Facility Standards

2.1A Facilities must comply with all federal, state and local regulations.

2.1.1A Adequate space must be provided for all facility operations to ensure patient comfort, safety, dignity, and privacy, as well as staff comfort and safety. Procedure areas must have sufficient space, be well-maintained, and be clean. There should be adequate space for personnel to access the patient and maintain the sterile field.

2.1.2A There must be adequate space for performing resuscitation in case of an emergency. This includes facility configuration and doorways for the emergency transport of patients from patient care areas and emergency exit of staff.

STANDARD – Areas (Physical Facility)

2.2A Area requirements include, but are not limited to:

2.2.1A General Areas

2.2.1.1A waiting, reception and patient/staff bathrooms;

2.2.1.2A patient education, consultation and examination areas; and

2.2.1.3A readily accessible hand washing/sanitation for staff.

2.2.2A Procedure Areas

2.2.2.1A pre-test/post-procedure areas within proximity of the procedure area;

2.2.2.2A substerile scrub area;

2.2.2.3A substerile entrance(s) must have:

i. dedicated or shared entrance between adjacent procedure rooms;
ii. entrance for patient transport from the prep area to the laboratory(s); and
iii. egress that connects to hallways leading to other clinical areas.

2.2.2.4A dedicated control room/area(s) must have:

i. leaded wall with a large leaded viewing window if the procedure room is contiguous with the control room;
ii. two-way intercom system; and
iii. desk space adequate to accommodate fluoroscopy monitors, hemodynamic /physiologic recording systems, etc.

2.2.2.5A procedure room/area(s) must have, but it not limited to the following:

i. positive airflow when a device is implanted, there is a skin incision, or prolonged procedure more than two hours;
ii. high flow oxygen and vacuum for suctioning;
iii. medical gas availability:

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- When general anesthesia is used, the following must be available in the procedure room:
  - nitrous oxide; and
  - waste gas lines.

iv. Room Utilities: Adequate utilities based upon the types of procedures and workload. These utilities include water taps, lighting, electrical outlets, emergency power, telephones, heating/cooling and ventilation.

v. General Room Lighting: Overhead and task lighting must be adequate to perform procedures, clinical evaluation and patient treatment. The overhead lighting must be able to be dimmed during fluoroscopy. It is recommended that the overhead lighting be controlled by a foot pedal used by the operating physician.

- Additionally, the procedure room must have surgical lighting for any procedure requiring access, device implantation, or that may require surgical intervention.

vi. The facility must have a plan that outlines the response to unexpected power loss or computer function, such as moving the patient to another procedure room in the immediate vicinity.

- When normal power is not available, emergency power should provide a minimum of 10 minutes of fluoroscopy, and at least one hour of backup power for the computers, monitoring equipment and ancillary equipment.
- There should be sufficient emergency power supply to run fluoroscopy for 10 minutes and run the remainder of the x-ray system components, including lighting, for at least 24 hours.
- The utilization of emergency power must be visible to the operator in the normal working position.
- An uninterruptible power supply for all computer equipment is required.
- X-ray equipment and computers should not require rebooting during the transition between normal and emergency power or during power line instabilities.

2.2.3A Interpretation/Dictation Areas

2.2.3.1A Adequately designed space must be provided for the interpretation of examination results and preparation of reports.

2.2.4A Storage Areas

2.2.4.1A Must ensure confidentiality of data and should be safe from fire, flood, power outages and natural disasters.

2.2.4.2A Adequate space must be provided for:

i. patient records, reports and digital data storage areas;
ii. administration records and support areas; and
iii. equipment/supply storage areas.

STANDARD – Equipment and Instrumentation

2.3A Equipment Type

2.3.1A Procedure-Specific Equipment – All facilities must have procedure-specific equipment (e.g., ablation systems, implantation devices, lead extraction, etc.) appropriate for the types and volume of procedures performed, including pediatric equipment and supplies, if applicable.

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2.3.2A Monitoring Equipment – All facilities must have routine monitoring equipment (e.g., ECG, blood pressure, pulse oximetry, etc.) appropriate for the types and volume of procedures performed, including pediatric equipment, if applicable.

2.3.3A Ancillary Equipment – (e.g., transesophageal echocardiography, ultrasound imaging, etc.) appropriate for the types and volume of procedures performed, including pediatric equipment, if applicable, must be available as appropriate.

2.3.4A Supplies – Adequate disposable supplies must be immediately available (e.g., catheters, wires, stents, balloons and embolic protection devices, sheaths, snares, intravenous fluids, needles, and syringes) appropriate for the types and volume of procedures performed, including pediatric equipment, if applicable, must be available as appropriate.

2.3.5A Medications – Pharmacologic agents (i.e., IV fluids, local anesthetics, analgesics, anxiolytics, medications to treat allergic or anaphylactic reactions, anticoagulation medications or reversal agents, sclerosants, embolizing agents) appropriate for the types and volume of procedures performed, including pediatric doses, if applicable, must be readily available for use during the procedure.

2.3.5.1A If sedation or anesthesia is administered refer to Standard 4.5A and also Standard 4.2A regarding medication safety.

2.4A Equipment, Instrumentation and Supplies Quality Control

2.4.1A There must be a comprehensive Quality Assurance (QA) program to provide a standard of measurement for system performance and the documentation of any variance thereof.

2.4.2A Equipment and instrumentation must be appropriate, in good working condition, and routinely inspected for safety and proper functionality per local, state, and/or federal regulations.

2.4.3A Preventive maintenance (PM) service is required according to the manufacturers' recommendations.

2.4.4A There must be a process to check inventory of disposable supplies (e.g., catheters, wires, balloons, stents, embolic protection devices, contrast) and medications to ensure they are not expired and are readily available during a procedure.

2.5A Quality Control Documentation

2.5.1A All equipment preventative maintenance, service and quality control results must be documented and reviewed. The reports must be signed and dated by the person(s) performing the tests.

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Section 3A: Fluoroscopy

STANDARD – Examination Areas

3.1A Rooms containing fixed fluoroscopes must have structural radiation-shielding (e.g., walls, doors, windows) that meet state requirements and specifications in the *National Council on Radiation Protection and Measurements Report No. 147: Structural Shielding Design for Medical X-Ray Imaging Facilities*. For rooms with dedicated mobile fluoroscopes (i.e., they are not moved between multiple rooms), a medical physicist must evaluate the potential need for structural shielding.

3.2A A qualified medical physicist must perform a radiation safety area survey to ensure that occupational workers and members of the public in all renovated or newly constructed rooms and adjacent areas are appropriately protected according to state regulations. This survey must be performed before first patient use for each new fixed angiographic imaging system. A documented radiation safety survey of the procedure room and adjacent areas that a State Radiation Program has accepted fulfills this requirement. A summary report of this survey must be provided to the Medical Director and/or Radiation Safety Officer, explicitly state that the existing shielding is or is not adequate and provide any necessary corrective action.

3.3A Fluoroscopy rooms must have signage to identify an area using x-ray equipment and restrictions of the public.

STANDARD – Equipment and Instrumentation

3.4A Fluoroscope

3.4.1A Fluoroscopes used for accredited procedures must comply with International Electrotechnical Commission (IEC) Standard 60601-2-43: Requirements for the Basic Safety and Essential Performance of X-ray Equipment for Interventional Procedures.

3.4.2A Fluoroscopes must be maintained and in good working condition and with appropriate documentation.

3.4.3A Fluoroscopes must be used for clinical applications as intended and defined in the manufacturer's documentation.

3.4.4A Fluoroscopes must be tested as described in Standard 3.5A.

STANDARD – Equipment and Instrumentation Quality Control

3.5A Fluoroscopic system quality control testing must include a comprehensive evaluation of the system components, image performance, and radiation output limits as outlined in the Suggested State Regulations for Control of Radiation (CRCPD) SSR, Part F, Medical Diagnostic and Interventional X-ray and Imaging Systems (2015) or comply with state health-code regulations.

3.5.1A A qualified medical physicist must complete the performance evaluations at equipment installation and annually or at the state-required frequency if that is more frequent. Equipment performance evaluations should include radiation output measurements, system quality control tests and image quality performance measurements.

3.5.2A Preventive maintenance (PM) service is required per the manufacturers' recommendations or at least annually for each fluoroscope.

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3.5.3A All equipment and instrumentation must be routinely inspected for safety and proper functionality, and records of the inspections must be kept on file.

3.5.4A Image monitor performance must be assessed using the Society of Motion Picture and Television Engineers (SMPTE) pattern, AAPM TG 272, AAPM TG 18 patterns, or equivalent; at a minimum, the maximum luminance and display uniformity must be measured.

STANDARD – Radiation Safety

3.6A Personnel

3.6.1A Fluoroscopic equipment may only be operated by individuals with the requisite training and credentials who meet all local, state and federal requirements and operate the equipment within their scope of practice.

3.6.2A Personnel Required Training and Experience:

3.6.2.1A All individuals in the fluoroscopic procedure room during the procedure must have documented radiation safety training that is approved by a medical physicist and that meets state requirements. Radiation safety training should align with the National Council on Radiation Protection and Measurements *Commentary 33 – Recommendations for Stratification of Equipment Uses and Radiation Safety Training for Fluoroscopy (2023)*.

3.6.2.2A In addition to radiation safety training, all individuals operating the fluoroscopy equipment must have machine specific training for each make and model of the fluoroscope operated.

3.6.3A Personnel Responsibilities:

3.6.3.1A Personnel responsibilities may include, but are not limited to:

i. All personnel in the room during fluoroscopic procedures must wear appropriate radiation protective apparel and use radiation safety equipment (i.e., lead shields and lead barriers) appropriate to the procedure. Mobile shields may be used in place of protective apparel if the shields are used as intended by the manufacturer and the medical physicist and radiation safety officer approve them (occupational dosimetry will likely need to be revised in this case).

ii. It is the individual's responsibility to comply with the occupational radiation monitoring requirements of the institution (e.g., badge placement, badge exchange, etc.).

iii. All personnel must be familiar with and follow their institution's radiation safety policies and procedures.

3.6.4A Continuing Education (CE) Requirements:

3.6.4.1A At least one hour of CE in radiation protection related to fluoroscopy must be obtained and documented every three years for individuals operating the fluoroscope.

3.7A Radiation Safety Program

3.7.1A General Radiation Safety

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3.7.1.1A There must be a comprehensive written radiation safety program that meets state and federal safety mandates and includes all relevant policies and procedures.

3.7.1.2A The radiation safety officer shall have oversite of and review all the following:

i. occupational dosimetry results (e.g., badges);

ii. personal radiation protective garment and accessory evaluation;

iii. availability and integrity of pull-down shields, table side shields, and any ancillary shields;

iv. patient radiation exposure summary reports; and

v. monthly summaries of patients/procedures exceeding the actionable levels.

3.7.2A Occupational and Patient Radiation Dose

3.7.2.1A The radiation safety program must include policies and procedures for monitoring and reviewing occupational and patient radiation doses.

3.7.2.2A Occupational Radiation Exposure and Monitoring

i. Personnel must comply with state regulations regarding radiation monitor placement, dosage monitoring, and reporting of dosage exposure.

ii. All persons likely to receive 10% or more of the annual occupational radiation dose limit must be monitored. However, it is strongly recommended that everyone involved in procedures be occupationally monitored.

iii. Personnel radiation devices must be provided by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited vendor.

3.7.2.3A Pregnant Staff

i. The facility must have a written policy or procedure for pregnant staff that addresses occupational dose monitoring. The policy and procedure must follow state and national regulations.

3.7.2.4A Patient Doses

i. Radiation dose rates must be monitored and set at the lowest reasonable settings consistent with satisfactory image quality for the procedure performed and the patient-specific variables.

ii. The site must have a policy identifying patient radiation dose indices that trigger patient education and follow-up for potential radiogenic tissue reactions.

iii. During fluoroscopically guided procedures, patient radiation dose indices must be monitored, and the monitoring staff must inform the operator when local thresholds are reached.

iv. Fluoroscopy radiation dose indices data per procedure must be recorded in the patient's medical record and be available for review. If the fluoroscope does not provide such data, the fluoroscopic exposure time and the total number of images acquired must be recorded in the patient's medical record.

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3.7.2.5A Protocol Modification

Comment: Protocol in this section is defined as the operational software-based program chosen by the end-user on the fluoroscope that determines the radiation output and image quality.

i. Any permanent changes to imaging protocols should be reviewed and approved by the site medical physicist and medical director, and documentation of any changes and reviews must be maintained.

3.7.2.6A Pregnant Patient

i. Patient Pregnancy Policy – For all clinical procedures, there must be a policy that ensures that patients who could be pregnant are identified. Pregnancy verification must be documented and contain the signature/initials of the patient and a member of the medical team verifying the information. This procedure must include an explanation of the proper steps to be taken if a patient may be or is pregnant.

- If a non-emergent procedure is needed for a pregnant patient, the responsible physician must discuss and document the potential risks, benefits, and options for alternative care.

3.7.3A Protective Equipment

3.7.3.1A The facility must have sufficient radioprotective apparel and ancillary shields for staff. The apparel and shields must be evaluated annually with documentation per institutional guidelines and policies and in compliance with state and federal guidelines.

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Section 4A: Safety

STANDARD – Patient and Staff Safety

4.1A All safety policies must adhere to state and federal regulations.

4.1.1A Safety policies must be consistently followed. Policy reviews must be documented annually.

4.1.2A There must be written policies and procedures for:

4.1.2.1A Patient Identification – Patients must be accurately identified using two independent patient-specific identifiers before procedure initiation.

4.1.2.2A Informed Consent – Informed consent must be obtained and documented in the patient's medical record consistent with the rules and regulations required by the hospital or facility.

4.1.2.3A Surgical/Procedural Time-Out – The facility must accurately identify and document the correct patient, site, and planned procedure before initiating procedure and sedation. The proper patient name or identification must also be on the imaging system.

4.1.2.4A Fire Safety Evaluation – A fire safety evaluation must be performed immediately before procedure initiation whenever there is potential for a flammable substance to be used in the presence of oxygen.

4.1.2.5A Infection/OHSA/Universal Precautions – All staff must adhere to universal precautions and infection control measures consistent with CDC and OSHA guidelines.

4.1.2.6A Incident Report/Adverse Events – The facility must have a process to document adverse events (i.e., contrast reactions, patient falls, emergencies).

4.2A Medication Safety

4.2.1A All medications, including sclerosants, embolizing agents, contrast, anesthetic agents, and pre-mixed pharmacologic agents, must be labeled with the medication and concentration. This includes all containers such as syringes, medicine cups, IV bags, and basins. The expiration date must also be verified.

4.2.2A Multiuse vials must be marked with the drug name, concentration, date of creation, initials of who made it, and expiration date.

4.2.2.1A A new needle and syringe must be used for every entry into the vial.

4.2.2.2A The vial stopper must be disinfected with an alcohol swab or equivalent antiseptic prior to entry.

4.2.2.3A To avoid contamination, venting needles or other objects may not be left in the stopper.

4.3A Contrast Safety

4.3.1A If intravascular contrast media are used, the facility must have written policies regarding the administration.

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4.3.2A Vascular access must be established or confirmed following the facility's protocol.

4.3.3A Low or iso-osmolar contrast must be used for intravascular injections.

4.3.4A Power or automated contrast injectors should be available and used when applicable.

4.3.5A Contrast material must be clearly labeled.

4.3.6A The maximum allowable contrast dose must be calculated for each patient before the procedure. The total contrast volume administered to the patient must be monitored in real-time and limited to as low as clinically possible. Staff should inform physicians when maximal limits have been reached.

4.3.7A Contrast name and volume administered must be documented in the patients' medical record.

4.3.8A Emergency equipment and medications must be immediately available to treat adverse events related to contrast media administration.

4.3.9A Policies must be in place for prophylaxis and treatment of patients with contrast allergies/reactions.

4.3.10A A policy must be in place for the management of patients at risk for or presenting with chronic kidney disease (CKD).

4.4A Emergency Equipment

4.4.1A All local, state, and federal regulations for emergency medical care must be followed. In the absence of such regulations, current American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care must be followed.

4.4.2A There must be at least one Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS) certified staff member on-site and immediately available as long as patients are being treated in the facility.

4.4.3A All facilities must have a medical emergency response plan, equipment, medications, and supplies appropriate for the types and volume of procedures performed, including pediatric equipment and supplies, if applicable.

4.4.4A The emergency response cart (crash cart) or kit must be immediately available and an appropriate number for the volume of procedures performed. The emergency response cart must include, at a minimum, the following:

4.4.4.1A defibrillator/automated external defibrillator (AED) with appropriate pad size available along with a backup defibrillator;

4.4.4.2A oxygen tanks or wall-mounted oxygen sources with appropriate-sized airways, cannulae and masks;

4.4.4.3A emergency medications in compliance with current ACLS or PALs guidelines;

4.4.4.4A intubation, suction equipment, and supplies according to the American Society of Anesthesiology (ASA) Guidelines;

4.4.4.5A equipment and supplies for starting and maintaining intravenous access according to the American Society of Anesthesiology (ASA) Guidelines;

4.4.4.6A The emergency response cart or kit must be checked at least monthly, with documentation to ensure all expected items are present and that supplies/medications are not expired.

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4.4.5A All emergency equipment must be clearly labeled and be for emergency use only.

4.4.6A Emergency equipment and medications must be secured with a disposable plastic lock.

4.5A Anesthesia

4.5.1A If sedation or anesthesia is administered, the facility must have written policies regarding their use that are in accordance with local/state guidelines and anesthesia guidelines. In the absence of such guidelines, the American Society of Anesthesiologists (ASA) Guidelines must be followed.

4.5.2A If moderate sedation is administered, physician/advanced practice provider certification must be documented.

4.5.3A At least one person in the procedure room must have Advanced Cardiac Life Support (ACLS) certification or Pediatric Advanced Life Support (PALS) certification for pediatric patient populations.

4.5.4A During sedation and anesthesia, there must be methods to assess the patient's level of consciousness pre-procedure and throughout the procedure.

4.5.5A At a minimum, the following monitoring equipment must be available with documentation if utilized:

4.5.5.1A non-invasive blood pressure;

4.5.5.2A pulse oximetry;

4.5.5.3A ECG monitoring; and

4.5.5.4A capnography (CO2) monitoring, if applicable.

4.5.6A Sedation and anesthetic agents must be clearly labeled with content, concentration and expiration date.

4.5.7A The type and level of sedation/anesthesia (e.g., moderate, deep, general anesthesia) must be documented in the patient's medical record.

4.6A Sterilization of Medical Instruments

4.6.1A The reuse of an FDA-approved single use device is not permitted unless it is done in compliance with FDA requirements.

4.6.2A Single and multiple-use products must be used before the expiration date.

4.6.3A Products approved by the FDA for multiple uses must be re-sterilized by a process approved by the FDA or Center for Disease Control (CDC), as applicable.

4.6.4A If sterilization is performed on-site, the facility must have a written policy. The policy must include, but is not limited to:

4.6.4.1A comprehensive training requirements for all staff assigned;

4.6.4.2A reprocessing instructions (provided by the instrument/sterilization manufacturer);

4.6.4.3A sterilizer maintenance as needed with records of service;

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4.6.4.4A description of quality control tests per manufacturer's recommendation and documentation thereof;

4.6.4.5A instructions for process monitoring and reporting;

4.6.4.6A instructions for visual inspection of packaging materials including heat-sensitive indicators inside each package treated with steam sterilization;

4.6.4.7A results of periodic biological monitoring performed at least weekly;

4.6.4.8A retainment of sterilization records for a period that complies with the CDC standards (e.g., three years), statutes of limitations and state and federal regulations; and

4.6.4.9A an established blood-borne pathogen exposure control plan must be in accordance with OSHA Blood-borne Pathogens Standards, and universal precautions must be used.

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Section 5A: Administrative

STANDARD – Patient Confidentiality

5.1A All facility personnel must ascribe to professional principles of patient-physician confidentiality as legally required by federal, state, local or institutional policy or regulation.

STANDARD – Patient or Other Customer Complaints

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

STANDARD – Primary Source Verification

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

STANDARD – Record Retention

5.4A All medical records, including archived images, must be retained in accordance with applicable state or federal guidelines for medical records, generally five to seven years.

STANDARD – Information Security

5.5A Information technology security must be maintained according to state and federal regulations.

Sample documents are available for each of the required policies listed in Section 5A on the IAC website at intersocietal.org/helpful-resources/sample-documents-repository.

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Part B: Process

Section 1B: Procedures and Protocols

STANDARD – Procedure Overview

1.1B The procedure overview described below is not intended to be a comprehensive list of requirements to perform a case, nor does it list every step necessary for every patient. It represents an overview of the general steps to perform a typical elective case in order to provide a context for the overall requirements of this accreditation program. A facility may find it helpful to use this description to create an institutional template to be used as a reference when analyzing outcomes. The following basic standards apply to both percutaneous carotid stenting and transcarotid stenting. Where indicated, each form of revascularization may have individual requirements that are unique to the specific procedure or credentialing recommendations.

1.1.1B The facility must assure that appropriate staff members with BLS and ACLS certification are present during the procedure.

1.1.2B Appropriate staff must be available to assist the patient should an adverse event occur during the procedure and/or during recovery.

STANDARD – Procedure Requirements

1.2B Prior to performance of the procedure:

1.2.1B An adequate supply of devices approved by the FDA for marketing or investigational use must be available. This includes, but is not limited to: interventional guide wires, diagnostic catheters, guiding catheters, angioplasty balloons, distal protection devices and carotid stents.

1.2.2B Appropriate pharmacologic agents must be readily available for use during the procedure.

1.2.3B Proper identification of the patient and planned procedure (e.g., target vessel) must be carried out prior to puncture according to national patient safety goals and the proper patient name or identification (ID) must be present on the imaging system.[1]

1.2.4B History and physical exam must be performed and should be in the chart and include documentation of relevant medications, allergies and bleeding disorders.

1.2.5B Independent neurologic assessment, National Institutes of Health Stroke Scale (NIHSS) and modified Rankin Scale (mRS) scores must be documented.

1.2.5.1B Patients undergoing percutaneous (carotid stenting and TCAR) will undergo independent neurologic assessments prior to and following the procedure to document the functional performance status and neurological examination and evaluate for any adverse neurological events.

1.2.6B Facility testing should be carried out including hemoglobin, hematocrit, platelet count, blood urea nitrogen (BUN), creatinine (within 30 days of the procedure) and pregnancy test (in women of childbearing age).

1.2.7B Imaging assessment of the cerebral parenchyma must be performed for patients with recent symptoms (stroke or cerebral transient ischemic attack [TIA]).

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1.2.8B Imaging of the intra and extracranial carotid and vertebral circulation should be performed for both symptomatic and asymptomatic patients using either catheter or noninvasive angiography. For TCAR, duplex assessment of the common carotid artery should include depth from the skin, diameter, calcification, degree of atherosclerosis, and distance from the clavicle to the carotid bifurcation.

1.2.9B The current standard treatment for antiplatelet agents/antithrombotic therapy should have been administered. At this time, the current standard is a dual antiplatelet regimen consisting of aspirin and either clopidogrel or alternative second antiplatelet agent.

1.2.10B The facility must have a process to address intra-procedural complications, including development of a new neurological deficit during the procedure.

1.3B During the performance of the procedure:

1.3.1B Cardiac pacing supplies and equipment must be available.

1.3.2B Cardiovascular medications must be available.

1.3.3B Physiologic monitoring must include continuous ECG, blood pressure and pulse oximetry. Capnography may be used (if appropriate).

1.3.4B Intravenous access for administration of fluids and medications must be in place.

1.3.5B Patient radiation dose must be monitored during the procedure.

1.3.6B For percutaneous procedures, the stent delivery sheath or guiding catheter should be connected to an airless flush system. For TCAR, the sheath is connected to a reverse flow system.

1.3.7B Availability and familiarity with a full range of interventional catheters, guide wires, stents and balloons is required. TCAR requires surgical equipment to achieve safe and adequate access to the carotid artery.

1.3.8B Quality imaging is required for both carotid stenting and TCAR procedures.

1.3.8.1B Quality imaging is necessary with digital subtraction angiography and road mapping capability as well as the ability to provide multiple orthogonal views with an adequately large image receptor for the operator to visualize the procedure. Appropriate imaging needs to be available and adapted to the OR setting.

1.3.8.2B The carotid artery stenosis must be measured using NASCET[4] criteria prior to the decision to perform revascularization. Baseline ipsilateral two-view carotid and cerebral angiography must be performed for percutaneous procedures.

1.3.8.3B For TCAR, baseline ipsilateral two-view carotid angiography is required. Cerebral angiography may be done for TCAR but is not required based on the current standard of practice and TCAR device manufacturer recommendations.

1.3.8.4B The use of electronic calipers (if available on the system), is required to quantitatively measure the percent of the stenosis to validate the clinical necessity for the procedure. Quantitative electronic measurements must use the post bulbar internal carotid artery diameter as the reference vessel, as per NASCET.[4]

1.3.9B Adequate anti-coagulation should be confirmed with activated clotting time (ACT) > 250 seconds or per ACT site local standards prior to crossing the lesion.

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1.3.10B For percutaneous procedures, an embolic protection device should be placed (if feasible).

1.3.11B Pre-dilation of lesion should be considered (if needed).

1.3.12B Deploy the stent.

1.3.13B Post-dilation should be considered (if needed).

1.3.14B Remove embolic protection following stent deployment.

1.3.15B Perform post stent deployment carotid (required for percutaneous and TCAR) and cerebral angiogram (required for percutaneous, suggested for TCAR) to check for stent patency, and to evaluate for distal emboli.

1.4B Following the performance of the procedure:

1.4.1B For patients in whom general anesthesia has not been used, perform and document post-procedure basic neurologic evaluation to assess for new neurologic deficits prior to moving the patient off the table. If general anesthesia has been used, the neurologic exam must be performed as soon as the patient is able to participate in the exam.

1.4.1.1B The facility must have a protocol in place to address post-procedure neurologic deficits.

1.4.1.2B Regardless of procedural access route, the facility must have a protocol in place to evaluate and potentially treat an intracranial large vessel occlusion that occurs as a complication of carotid stenting.

1.4.1.3B Assessment of blood pressure and the status of the puncture site.

1.4.1.4B Blood pressure must be controlled post-procedure according to the facility protocol.

1.4.2B A post-procedure note in the patient's chart must be generated summarizing the procedure and addressing any immediate complications and the patient's status at the end of the procedure.

1.4.2.1B Radiation usage as recorded by the angiographic system (i.e., reference point air kerma [mGy], Air kerma-area product [mGy*cm^2], and fluoroscopy time) during the procedure must be documented in the final procedure report.

1.4.3B The patient must be moved to an appropriate setting such as a neuro critical care/ intensive care/step down unit with the equipment and trained personnel necessary to perform vascular, hemodynamic and neurological monitoring and stroke assessment.

1.4.4B Document post-procedure independent neurologic assessment (including a NIHSS and modified Rankin score) within approximately 24 hours and also within 60 days.

1.4.4.1B If there is any worsening from the pre procedure NIHSS (> 2 point change) or modified Rankin score or new neurological deficit, a neurologic consultation must be performed by a neurologist or if a neurologist is not available a physician with neurologic expertise.

1.4.5B Imaging of the stent must be performed within 60 days after the carotid artery stent procedure. Duplex ultrasound is the recommended imaging study.

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STANDARD – Procedure Volumes

1.5B The procedure volume must be sufficient to maintain proficiency in procedure performance. A facility may choose to be accredited for percutaneous carotid stenting, TCAR or both. The QI requirements for percutaneous carotid stenting are identical for TCAR, but the procedures are sufficiently different that procedure volumes and outcomes are tracked separately.

1.5.1B The facility must have specific privileging requirements for individual operators to perform carotid stenting, carotid endarterectomy as well as endovascular procedures including TCAR. Facility privileging requirements may exceed the requirements in these Standards.

1.5.2B Percutaneous Procedures

1.5.2.1B To be eligible for consideration for percutaneous accreditation, a facility must have performed 25 percutaneous carotid stent procedures over the preceding three-year period.

1.5.2.2B If the facility has performed fewer than 25 percutaneous stent procedures over the preceding three-year period at least one operator must have performed 15 percutaneous stent cases (either in training or during post training experience as the primary operator) preferably with an embolic protection device in the past three years with adequate outcomes as defined in Quality Improvement (QI) Standard 4.2C.

1.5.3B TCAR Procedures

1.5.3.1B To be eligible for consideration for TCAR accreditation, a facility must have performed 25 TCAR procedures over the preceding three-year period.

1.5.3.2B If the facility has performed fewer than 25 TCAR stent procedures over the preceding three-year period, at least one operator must have performed 15 TCAR stent cases (either in training or during post training experience as the primary operator) as defined in Quality Improvement (QI) Standard 4.2C.

1.5.4B The facility QI Program must include all elective cases.

1.5.4.1B Reporting of additional emergent cases which may involve additional intracranial or cervical advanced techniques should be given consideration.

Comment: The application review will recognize and take into consideration that a higher complication rate may be reported for the emergent cases.

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Part C: Quality Improvement

Section 1C: Quality Improvement Program

STANDARD – QI Program

1.1C The facility must have a written Quality Improvement (QI) Program to evaluate all types of procedures performed in the facility on an ongoing basis. The QI program must include the QI measures outlined below but may not be limited to the evaluation and review of:

1.1.1C procedure/test appropriateness;

1.1.2C technical quality and performance of the procedure;

1.1.3C patient safety;

1.1.4C procedure outcomes (including complications and any adverse events);

1.1.5C physician performance (per facility based on scope of practice); and

1.1.6C medical record completeness and timeliness.

STANDARD – QI Oversight

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

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Section 2C: Quality Improvement Measures

STANDARD – General QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C through 2.1.6C. All measures described need to be measured for consecutive cases over a period of time. A minimum of 30 cases must be reviewed annually.

2.1.1C Procedure/Test Appropriateness

2.1.1.1C The QI Program must include clinical indications including risk category and outcome measures.

2.1.2C Technical Quality and Performance of the Procedure

2.1.2.1C The performance of all medical, technical, and ancillary staff must be assessed as part of the QI program, per facility protocol based on scope of practice.

2.1.3C Patient Safety

2.1.3.1C Infection control measures consistent with CDC and OSHA guidelines.

2.1.3.2C Adherence to National Patient Safety Goals must be documented.

2.1.3.3C There must be a program in place to assess and evaluate patient and personnel radiation dose.

2.1.3.4C The QI program must include assessment of the safety of the procedures being performed.

2.1.3.5C Participation in a national registry for all patients is strongly recommended.

2.1.4C Physician Performance

2.1.4.1C The QI program must include assessment of the performance of physicians regarding the quality of medical practice (such as report accuracy, appropriateness of care, effectiveness of performing the procedure) and physician behaviors (communication and professionalism). Areas that may be assessed include but are not limited to:

i. peer review;
ii. correlation of interpretation with other diagnostic studies, pathology/surgical results and/or patient outcomes;
iii. time from completion of procedure to distribution of final report;
iv. referring physician satisfaction and feedback; and
v. patient satisfaction and feedback.

2.1.5C Procedure Outcomes (including complications or any adverse events):

2.1.5.1C For purposes of Quality Improvement (QI) and reporting of outcomes, the carotid stent procedure begins when the guide catheter or sheath for stent placement has been inserted into the patient. Deployment is considered successful if the stent has been placed across the target lesion per the instructions for use.

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2.1.5.2C The program must show evidence of improvement activities or, if an assessment confirms acceptable quality of a measure, the program must demonstrate improvement by selecting a new or an additional area for assessment.

2.1.5.3C The program should have pre-defined indicators of quality and pre-defined thresholds that indicate the need for corrective action. Comparison with external benchmarks are desirable.

2.1.5.4C The program must include outcome measures.

i. Outcome data is most widely available for treatment of carotid bifurcation disease secondary either to atherosclerosis, post endarterectomy restenosis or radiation induced stenosis. Therefore, the outcome benchmarks used in this program are intended to be applied only to cases treated for these indications. However, all cases should be included in outcome monitoring.

ii. Outcomes data must be consistent with national benchmarks and where there are no benchmarks the data must be used to internally improve processes and procedures. For facilities not meeting the benchmarks described below in items 4.4C and 4.5C, a plan for improvement must be submitted and documented improvement provided within 12-18 months before full accreditation will be considered.

2.1.5.5C A process to confirm the accuracy of the percentage of stenosis reported for symptomatic and asymptomatic patients warranting the intervention must be in place.

i. If quantitative electronic measurements are used to determine the stenosis percentage, there must be a process to assess differences between the subjectively reported and the electronic measurements. Ideally, the quantitative (electronic) and subjective measures of stenosis severity should be very similar or identical.

ii. If subjective measurements are used to determine the need for treatment, deviations between the subjective and electronic measurement warrant a documented explanation and where appropriate, documented corrective action.

iii. 90% of patients should meet facility defined clinical and degree of stenosis indications as defined in the QI program.

2.1.6C Medical Record Completeness and Timeliness

2.1.6.1C Time from completion of procedure to signature of final documentation must be completed within two business days.

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Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

3.1C Quality Improvement (QI) meetings must be documented.

3.1.1C All relevant personnel assessed in the QI Program must participate in periodic facility meetings to review findings and determine actions for improvement of performance. At a minimum, these meetings must occur at least every six months.

3.1.2C Every stroke and death must be reviewed during these meetings.

3.1.3C All relevant personnel must be included in periodic facility meetings to provide in-service education containing relevant topics. Topics should include safety procedures, technical information and improvements to be made based on quality assessments and other information.

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Section 4C: Quality Improvement Documentation

STANDARD – QI Documentation

4.1C QI documentation (policies, reports, records, etc.) must be maintained at the facility and made available to all personnel.

4.1.1C The Medical Director and appropriate staff must review and maintain minutes or reports of QI evaluations and document (as applicable) corrective measures taken.

4.1.2C The facility must have a mechanism in place to track each carotid stent procedure performed including but not limited to patient identification, date of birth, date of procedure, the clinical indication, pre- and post-procedure independent neurologic assessment including NIHSS and mRs, use of embolic protection device use, degree of stenosis improvement post-procedure and any procedure complications that occur within 60 days after the procedure.

4.1.3C A written process to contact all patients for the follow-up neurological assessment within 60 days after the procedure with documentation that the process is being performed.

STANDARD – Reporting of Outcomes

4.2C Initial Accreditation

4.2.1C Many facilities may have low volumes of procedures when they apply for initial accreditation. This low volume makes statistical analysis of complication rates unreliable and may penalize a low volume facility that has a complication early in its experience. In addition, a new facility may not have performed any procedures (although at least one individual physician must have a minimum experience of 15 procedures in order to apply for accreditation). Similar to the technique used to evaluate the outcomes of vascular surgeons performing carotid endarterectomy[8] facilities applying for initial accreditation will be evaluated on a minimum of 100 patients (50 symptomatic and 50 asymptomatic) in the previous three years. If the facility has not performed 100 procedures in the three years prior to initial accreditation, the facility will be provided up to 50 complication-free hypothetical procedures in each indication category. For example, a facility with a low volume will be given up to 100 hypothetical procedures (50 symptomatic and 50 asymptomatic) without a death or stroke.

4.3C Reaccreditation

4.3.1C After initial accreditation the facility will be evaluated only on cases performed since the initial accreditation. Each facility will be provided one time with 50 complication-free hypothetical procedures in each indication category. The facility will then create a running total of 50 procedures in each indication category. The outcomes must be tracked both by actual procedures as well as actual procedures plus hypothetical procedures. The overall combined analysis is what will be used to determine if a facility meets the benchmarks. However, complications and complication rates in actual procedures must be reviewed to prevent the hiding of an unacceptably high complication rate within the moving 50. For each actual procedure performed a hypothetical procedure will be dropped from the total until all hypothetical procedures are removed and outcomes are then based solely on actual procedures performed by the facility.

4.3.1.1C After the facility has performed 50 procedures in an indication category, analysis of outcomes for the facility for that category will be based on the total actual procedures performed since the initial accreditation, and the ability to use any hypothetical cases will be removed.

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4.3.1.2C After a facility has performed 100 actual procedures in an indication category it will be evaluated on the running total of the most recent 100 procedures in that category.

4.4C Outcome Measures: Benchmarks by Indications for Procedures

4.4.1C Elective Symptomatic Carotid Stenosis – defined as experiencing acute TIA symptoms or completed ischemic stroke within six months of the intervention, but neurologically stable for at least 24 hours.

4.4.1.1C Benchmark: < 6% all stroke and death within 30 days of the procedure. Adverse events noted on the first neurological assessment post procedure (21-60 days) must be counted as a complication. (See Appendix for definition of stroke)

Comment: In order to apply for accreditation, if the facility exceeds the benchmark of 6% but does not exceed 10%, a plan for improvement must be submitted and documented improvement provided within 12-18 months before full accreditation will be considered. Benchmarks must be met within three years.

4.4.2C Elective Asymptomatic Carotid Stenosis

4.4.2.1C Benchmark: < 3% all stroke and death within 30 days of the procedure. Adverse events noted on the first neurological assessment post procedure (21-60 days) must be counted as a complication. (See Appendix for definition of stroke)

Comment: In order to apply for accreditation, if the facility exceeds the benchmark of 3% but does not exceed 4%, a plan for improvement must be submitted and documented improvement provided within 12 months before full accreditation will be considered. Benchmarks must be met within three years.

4.5C Outcome Measures: Technical

4.5.1C Peri/Immediate Post-Procedure

4.5.1.1C Successful Stent Deployment – Deployment is considered successful if the stent has been deployed across the target lesion per the instructions for use.

i Benchmark = > 95% of the cases have successful stent deployment.

4.5.1.2C Improvement in degree of stenosis – post procedural % angiographic stenosis by North American Symptomatic Carotid Endarterectomy Trial (NASCET) methodology.[4]

i Benchmark = > 95% of the cases have improvement in the degree of stenosis.

4.5.1.3C Measurement of neurological outcome by an independent examiner (defined as the person performing the assessment that is not the operator or any other person listed on the procedure documentation).

i Modified Rankin Scale at 24 hours (or discharge)

ii NIHSS at 24 hours

iii Neurological Consult – If there is any worsening from the pre procedure NIHSS (> 2 point change) or mRS or new neurological deficit, a neurologic consultation must be performed by a neurologist or if not available a physician with neurologic expertise.

- Benchmark = 100% at 24 hours for pre and post-procedure measurement of NIHSS and mRS.

4.5.1.4C Post-procedure follow-up must be performed within 60 days.

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i 80% of patients will have 60-day outcomes follow-up data

ii Imaging of the stent must be performed within 60 days for patency. Duplex ultrasound is the recommended imaging study.

Comment: If stent occlusions occur in two or more patients at post-procedure follow-up (i.e., within 60 days) within a three-year review cycle then a process must be in place for review and reporting of causative factors and methods for improvement.

iii Independent neurological assessment: Measurement of neurological outcome within 60 days.

- Modified Rankin scale
- NIHSS
- Neurological Consult: If there is any worsening from the pre procedure NIHSS (> 2 point change) or Rankin or new neurological deficit, a neurologic consultation must be performed by a neurologist or if a neurologist is not available a physician with neurologic expertise.

4.6C Administrative Quality Assessment

4.6.1C The QI Program must be in place to assess and improve the administrative quality of the facility's operation. Administrative areas that may be assessed include, but are not limited to:

4.6.1.1C scheduling back logs;

4.6.1.2C patient wait times;

4.6.1.3C accuracy of patient information during scheduling;

4.6.1.4C completeness of documentation;

4.6.1.5C late reports;

4.6.1.6C time from completion of procedure to distribution of final report;

4.6.1.7C patient satisfaction and feedback;

4.6.1.8C referring physician satisfaction and feedback; and

4.6.1.9C patient education: on individual risk factors, smoking cessation, signs and symptoms of stroke and calling 911, importance of follow-up after discharge, review of discharge medications including importance of adherence to antithrombotic therapy.

4.7C Technical Quality Assessment

4.7.1C The QI Program must include assessment of the technical quality of the images and procedures being performed. Areas that may be assessed include but are not limited to:

4.7.1.1C image quality;

4.7.1.2C image display/labeling; and

4.7.1.3C documentation of adverse technical events such as equipment or device failure.

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4.8C Physician Performance Quality Assessment

4.8.1C The QI program must include assessment of the performance of physicians regarding the quality of medical practice (such as report accuracy, appropriateness of care, effectiveness of performing the procedure) and physician behaviors (communication and professionalism). Areas that may be assessed include but are not limited to:

4.8.1.1C peer review;

4.8.1.2C correlation of interpretation with other diagnostic studies, pathology/surgical results and/or patient outcomes;

4.8.1.3C time from completion of procedure to distribution of final report;

4.8.1.4C referring physician satisfaction and feedback; and

4.8.1.5C patient satisfaction and feedback.

4.9C Patient Radiation Dose Review/Evaluation

4.9.1C The QI program must include an assessment of patient dose as compared to published guidelines. At a minimum the program must meet the criteria outlined in Guidelines for Patient Radiation Dose Management.[13]

Comment: The radiation dose thresholds outlined in the reference are trigger values set at a prudently low value such that the possibility of an injury at the threshold level is highly unlikely. There is no implication that exceeding a threshold will always cause an injury.

4.9.1.1C When radiation dose thresholds are exceeded, the facility must have a process in place for patient monitoring and follow-up.

4.9.1.2C All steps in the evaluation and follow-up process must be documented.

4.9.2C Other Diagnostic Angiographic Procedures – Facility should have processes in place for monitoring cerebral diagnostic arteriography with complications not to exceed published guidelines.[10]

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Appendix

QUALITY IMPROVEMENT MEASURES: INDICATIONS AND ADVERSE EVENTS

I) INDICATIONS FOR CAROTID ANGIOPLASTY AND/OR STENTING

Definition: Symptomatic carotid stenosis is defined as a carotid stenosis associated with an ipsilateral cerebral or retinal TIA or infarction within the past six months.

Comment: Centers for Medicare and Medicaid Services (CMS) reimbursement policy requires patients to meet specific indications (www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=201). Currently, CMS policy requires that all patients are high surgical risk (see below) and have a pre-procedure mRS < 2. For symptomatic patients current CMS reimbursement policy requires > 70% angiographic diameter stenosis using NASCET[4] criteria. For patients participating in an approved trial, the stenosis may be > 50%. For asymptomatic patients, current CMS reimbursement policy requires patients to be enrolled in an approved trial and have > 80% angiographic diameter stenosis using NASCET[4] criteria.

High Risk Category as defined by CMS:

1. congestive heart failure (CHF) class III/IV;
2. left ventricular ejection fraction (LVEF) < 30%;
3. unstable angina;
4. contralateral carotid occlusion;
5. recent myocardial infarction (MI);
6. previous CEA with recurrent stenosis;
7. prior radiation treatment to the neck; and
8. other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH and MAVERIC II.

IAC Carotid Stenting recognizes that not all patients fall into one of the above categories and CMS may alter reimbursement policy as more data are available. Other potential indications are listed below.[3] However, the presence of one or more of these potential anatomic and medical conditions in a patient does not imply that carotid angioplasty and/or stenting is indicated for that patient. Appropriate therapy is determined by symptoms, severity of stenosis and an overall assessment of the risks and benefits of the procedure compared to alternative medical and interventional therapies.

1. Stenosis that is surgically difficult to access (e.g., high bifurcation requiring mandibular dislocation).
2. Stenosis in a patient with significant medical disease that would make the patient high risk for surgery
3. Stenosis and one of the following conditions:
   a. significant tandem lesion that may require endovascular therapy;
   b. radiation-induced stenosis;
   c. restenosis following CEA;
   d. refusal to undergo CEA following proper informed consent;
   e. stenosis secondary to arterial dissection;
   f. stenosis secondary to fibromuscular dysplasia (stents rarely, if ever, indicated);
   g. stenosis secondary to vasculitis (stents rarely, if ever, indicated).
4. Stenosis associated with contralateral carotid artery occlusion requiring treatment before undergoing cardiac surgery.
5. Severe underlying carotid artery stenosis revealed after recanalization of carotid occlusion following thrombectomy/thrombolysis for acute stroke (presumed to be the etiology of the treated occlusion) or to enable thrombectomy/thrombolysis for acute stroke.
6. Pseudoaneurysm.

II) ADVERSE EVENTS

1. All stroke: For purposes of IAC Carotid Stenting Quality Improvement (QI) and comparing facility outcomes to national benchmarks, a stroke is defined as an ischemic or hemorrhagic brain injury causing a neurologic deficit that persists for more than 24 hours.

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a. cerebral infarction/ ischemic stroke;
b. intracranial hemorrhage/hemorrhagic stroke;
c. unknown type of stroke (no imaging performed).

2. TIA (symptoms < 24 hours) with or without neuroimaging evidence of acute infarction is not considered a stroke for IAC Carotid Stenting QI and comparison to national benchmarks, although it may be considered a stroke for research reporting purposes.
3. Other neurologic (edema/hyperperfusion syndrome).
4. All death.
5. MI.
6. Other cardiac event:
   a. heart failure or pulmonary edema;
   b. arrhythmia requiring cardioversion, pacemaker insertion, or ICD insertion;
   c. hypotension requiring parenteral medications for > 24 hours post-procedure.
7. Renal failure with new requirement for dialysis.
8. Infection related to procedure requiring antibiotics.
9. Angiographic complications:
   a. dissection requiring treatment;
   b. urgent surgery required for technical problems with stent deployment or placement;
   c. intracranial embolization.
10. Bleeding requiring blood transfusion.
11. Arterial access:
    a. pseudoaneurysm requiring treatment with thrombin injection and/or compression during hospitalization;
    b. access site injury requiring open surgical repair.
12. Vessel thrombosis, peripheral embolization, or ischemia of an extremity.
13. Other:
    a. unexpected intubation or resuscitation;
    b. contrast reaction.

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Artificial Intelligence (AI) Guidance Document

To assure the quality and safety of care delivery when using AI applications for direct-patient care (clinical*) purposes, each facility should create and follow policies and procedures that address:

1. Training for personnel who use AI;
2. Security of AI software, updates, HIPAA considerations, etc.;
3. AI for Quality Improvement (if applicable);
4. Appropriate use for each AI application; and
5. Governance (authority to make decisions regarding AI implementation).

*Clinical use of AI includes image acquisition, image processing/enhancement, image interpretation, report generation, risk assessment of prognosis, patient history, identification of critical values/results and equipment quality control.

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