IAC®
INTERSOCIETAL
ACCREDITATION
COMMISSION
CARDIOVASCULAR CATHETERIZATION

The IAC Standards and Guidelines for Cardiovascular Catheterization Accreditation

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Introduction

The Intersocietal Accreditation Commission (IAC) is a non-profit organization that accredits facilities that perform adult and/or pediatric diagnostic and/or interventional cardiovascular catheterization procedures. Accreditation in cardiovascular catheterization may include one or more of the following testing areas: adult diagnostic catheterization, percutaneous coronary invention (PCI), valve interventions, structural heart interventions, complex adult congenital heart disease (ACHD), pediatric cardiovascular catheterization. IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide. The IAC program for accreditation in cardiovascular catheterization is dedicated to ensuring quality patient care and promoting health care and support through one common mission: *Improving health care through accreditation*®.

This program is designed to accredit facilities that perform cardiovascular catheterization procedures by ensuring that the facility meets benchmarks for quality based on resources, training and outcomes. Cardiovascular catheterization procedures may be appropriately performed for many indications related to the diagnosis and treatment of acquired and congenital diseases of the heart.[1,2,3] The outcome benchmarks used in this program are intended to be applied only to cases treated for indications related to cardiovascular catheterization. A facility that meets the outcome benchmarks for these most common indications will most likely provide adequate outcomes for cardiovascular catheterization procedures performed for less common indications.

A facility performing cardiovascular catheterization procedures must provide the appropriately credentialed staff, equipment, policies and procedures. All personnel using equipment associated with cardiovascular catheterization must be able to demonstrate familiarity and proficiency with the setup, operation and characteristics of the equipment employed at their site. Additionally, a facility performing cardiovascular catheterization procedures that routinely require the performance of transesophageal echocardiography, must do so in an IAC Echocardiography accredited facility.

Each facility must have a Medical Director and a Nurse Manager and/or Technical Manager. The facility may be comprised of dedicated and/or shared equipment and personnel resources (e.g., a dedicated cardiovascular catheterization laboratory and personnel, an interventional laboratory with shared equipment and personnel, a hybrid OR with dedicated and/or shared equipment and personnel, etc.). The facility must meet the organizational requirements defined in this document. The designation of the title of Medical Director, Nurse Manager and Technical Manager are for IAC accreditation purposes only. Those assigned in these roles for the purpose of accreditation must meet the training and experience requirements as outlined in the IAC Standards, but may also have oversight or dual responsibilities for other procedures other than those directly related to cardiovascular catheterization procedures. When more than one technical member is employed, the Technical Manager and/or Nurse Manager are responsible for supervision of the technical staff. If cardiovascular catheterization procedures are 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 [i.e., physician(s), advanced practice provider (s), nurse(s) and technologists(s)] 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 services for cardiovascular catheterization procedures. It is also designed to be used as an educational tool to improve the overall quality of the facility.

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

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

In addition to all Standards listed in this document, 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.

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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 one or more of the following:

1.1.1.1A Board certified in his/her specialty:

i. Initial certification by the American Board of Internal Medicine (ABIM) in interventional cardiology or the American Osteopathic Board of Internal Medicine (AOBIM) in interventional cardiology.

1.1.1.2A For diagnostic cardiovascular catheterization, board certified in his/her specialty:

i. Level II training in cardiac catheterization.[4,5]

1.1.1.3A For interventional cardiovascular catheterization, board certified in his/her specialty:

i. Level III training in cardiac catheterization.[4,5]

1.1.1.4A For pediatric cardiovascular catheterization, board certified in his/her specialty[9,16,25]:

i. certification by the American Board of Pediatrics (APB) in pediatric cardiology, by the Royal College of Physicians and Surgeons of Canada in pediatric cardiology, or by the American Board of Internal Medicine in adult congenital heart disease;
ii. additional training in pediatric cardiac catheterization and intervention (beyond what is typically obtained in categorical fellowship) or completion of pediatric cardiology fellowship prior to 2000; and
iii. should have a minimum of five years of experience in pediatric interventional cardiology.

1.1.1.5A When applicable, ACLS, PALS and BLS certification.

1.1.2A Medical Director Responsibilities

The Medical Director is responsible for implementing measures to achieve and maintain compliance with the Standards for all services provided, including compliance, radiation safety, outcomes, quality control and 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.

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1.1.2.2A Delegation, when appropriate, of the review of radiation safety standards to the Nurse Manager and/or Technical Manager, 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.

1.1.2.3A The review and oversight of the clinical practice of diagnostic and interventional cardiovascular catheterization and coronary artery procedural services.

1.1.2.4A Provide oversight and documentation of comprehensive Quality Improvement (QI) Program (refer to Section 1C: QI Program).

1.1.2.5A Demonstrate familiarity and proficiency with the setup and operation of all equipment associated with the diagnostic and interventional cardiovascular catheterization and coronary artery procedures performed in the facility.

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.

(See Guidelines on Page 20 for further recommendations.)

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 acquired and/or congenital heart disease that includes, but is not limited to, content that is directly related to the performance of cardiovascular catheterization procedures and/or acquired and/or congenital heart disease and/or coronary artery 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 (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CME requirement.). 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. certification by the American Board of Internal Medicine (ABIM) or American Osteopathic Board of Internal Medicine (AOBIM) in Interventional Cardiology; or
iii. certification by the American Board of Pediatrics (ABP) in Pediatric Cardiology or the Royal College of Physicians and Surgeons of Canada in Pediatric Cardiology.

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:

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1.2.1.1A Board certified in his/her specialty:

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

ii. initial certification by the American Board of Internal Medicine (ABIM) in interventional cardiology or the American Osteopathic Board of Internal Medicine (AOBIM) in interventional cardiology.

1.2.1.2A For diagnostic cardiovascular catheterization, board certified in his/her specialty:

i. Level II training in cardiac catheterization.[4,5]

1.2.1.3A For interventional cardiovascular catheterization, board certified in his/her specialty:

i. Level III training in cardiac catheterization.[4,5]

1.2.1.4A For pediatric cardiovascular catheterization, board certified in his/her specialty[6,9,25]:

i. certification by the American Board of Pediatrics (APB) in pediatric cardiology, by the Royal College of Physicians and Surgeons of Canada in pediatric cardiology, or by the American Board of Internal Medicine in adult congenital heart disease;

ii. have performed a minimum of 250 cardiac catheterizations, and if performing interventional procedures, at least 150 interventional procedures, as the primary operator or first assistant, during training, and/or in the first two years after completion of training, and/or in the previous three years of practice; and

iii. in addition, senior medical staff must participate in a minimum of 50 cases per year, and if performing interventional procedures, at least 25 interventions per year.

1.2.1.5A When applicable, ACLS, PALS and BLS certification.

1.2.1.6A Medical staff may also qualify by meeting the following:

i. have performed a minimum of 300 cardiovascular, catheter-based diagnostic procedures and, if applicable 250 interventional procedures during training and/or in the first two years after completion of training, or in the previous three years of practice;[5]

ii. have completed training and practiced cardiovascular catheterization for at least two years after completion of training; and

- demonstrate at least 75 percent of clinical practice devoted to acquired and/or congenital heart disease/disorders and/or coronary artery disease to include the following:
  - a minimum of 300 cardiovascular, catheter-based diagnostic and, if applicable, 250 interventional procedures during training and/or in the first two years after completion of training, or in the previous three years of practice.[5]

1.2.1.7A All physicians (including the Medical Director) performing cardiovascular catheterization procedures must be privileged by clear and concise requirements as outlined by their hospital privileging committee that include periodic review and documentation of credentialed staff according to published guidelines listed in Appendix A.

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Comment: The facility must have a plan in place for all non-certified medical staff to obtain an appropriate certification prior to the next accreditation cycle.

1.2.2A Medical Staff Responsibilities

The medical staff is responsible for performing the evaluation, management and treatment of coronary artery disease. Responsibilities include, but are not limited to:

1.2.2.1A Compliance with all of the facility's policies, procedures and/or protocols and to the Standards outlined in this document.

1.2.2.2A Equipment training and inspection to ensure safe operating conditions as specified by the manufacturer's guidelines and the Medical Director.

1.2.2.3A Demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the cardiovascular catheterization performed in the facility.

(See Guidelines on Page 20 for further recommendations.)

1.2.3A Continuing Medical Education (CME) Requirements

1.2.3.1A The medical staff must obtain at least 15 hours of Category I CME credits, relevant to acquired and/or congenital heart disease that includes, but is not limited to, content that is directly related to the performance of cardiovascular catheterization procedures and/or acquired and/or congenital heart disease and/or coronary artery 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 (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CME requirement.).

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;
ii. certification by the American Board of Internal Medicine (ABIM) or American Osteopathic Board of Internal Medicine (AOBIM) in interventional cardiology; or
iii. certification by the American Board of Pediatrics (ABP) in pediatric cardiology or the Royal College of Physicians and Surgeons of Canada in pediatric cardiology.

1.2.3.2A Documentation of CME credits must be kept on file and available for inspection.

STANDARD – Nurse Manager

1.3A The manager of the technical and nursing staff must be either an appropriately credentialed technologist (1.4A) and/or appropriately credentialed nurse and meet the required training and experience qualifications as outlined.

1.3.1A Nurse Manager Required Training and Experience

1.3.1.1A The Nurse Manager must be licensed and demonstrate an appropriate level of training and experience by meeting at least one of the following criteria:

i. Registered Nurse (RN);

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ii. Advanced Practice Nurse (APRN);

iii. advanced health care degree or bachelor of science in nursing (BSN) preferred;

iv. certification in interventional nursing specialty such as Cardiac Nurse Practitioner (NP-C), Cardiovascular Clinical Nurse Specialist (CNS), Cardiac Vascular Nursing (CVRN), Certified Radiology Nurse (CRN).

v. In addition to the credential of RN, the individual may acquire one or more of the following: Registered Cardiovascular Invasive Specialist (RCIS) with the Cardiovascular Credentialing International (CCI).

1.3.1.2A For Nurse Managers actively participating in cardiovascular catheterization procedures:

i. at least six months of experience in critical care and/or emergency room and/or cardiovascular catheterization nursing.

1.3.1.3A For adult cardiovascular catheterization:

i. Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) certification are required.

1.3.1.4A For pediatric cardiovascular catheterization:

i. Basic Life Support (BLS) and Pediatric Advanced Life Support (PALS) are required.

1.3.2A Nurse Manager Responsibilities

The Nurse Manager responsibilities may include, but are not limited to:

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

1.3.2.2A management of pre- and post-procedural care areas;

1.3.2.3A direct participation in the observation and care of patients undergoing cardiovascular catheterization procedures;

1.3.2.4A application of institutional guidelines for patient monitoring, medication administration, procedural sedation and patient safety;

1.3.2.5A managing staff competencies and proficiency in performing tasks required before, during, and after the procedure;

1.3.2.6A the delegation, when necessary, of specific responsibilities to the technical and/or nursing staff and/or ancillary staff;

1.3.2.7A verification of documentation of proper training and, at least annually, assessment of the competence of technical and/or nursing staff and/or any ancillary staff who report to the Nurse Manager; and

1.3.2.8A demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the cardiovascular catheterization procedures performed in the facility.

(See Guidelines on Page 20 for further recommendations.)

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1.3.3A Continuing Education (CE) Requirements

1.3.3.1A The Nurse Manager must obtain at least 15 hours of accredited CE relevant to acquired and/or congenital heart disease that includes, but is not limited to, content that is directly related to the performance of cardiovascular catheterization procedures and/or acquired and/or congenital heart disease and/or coronary artery disease and/or cardiovascular 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 (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CE requirement.).

1.3.3.2A All CE hours must be approved (i.e., American Nurses Credentialing Center [ANCC-Category I], AMA Category I) and/or obtain appropriate CE, Cardiovascular Credentialing International [CCI]-Cardiovascular CEU, Alliance of Cardiovascular Professionals [ACVP]-CEU, American Registry of Radiologic Technologists [ARRT]-Category A, American Society of Radiologic Technologists [ASRT], American Medical Association [AMA]). At least one contact hour in moderate sedation is required annually.

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

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

STANDARD – Technical Manager

1.4A The manager of the technical and nursing staff must be either an appropriately credentialed technologist and/or appropriately credentialed nurse (1.3A) and meet the required training and experience qualifications as outlined below.

1.4.1A Technical Manager Required Training and Experience

The Technical Manager must be licensed (where applicable) and demonstrate an appropriate level of training and experience by meeting one the following criteria:

1.4.1.1A A registered specialist with the Cardiovascular Credentialing International (CCI) meeting the following criteria:

i. Registered Cardiovascular Invasive Specialist (RCIS).

1.4.1.2A A registered radiologic technologist with the American Registry of Radiologic Technologists (ARRT) meeting one or more of the following criteria:

i. Cardiovascular-Interventional Radiography RT (CV); or
ii. Cardiac-Interventional Radiography RT (CI).

1.4.1.3A A registered specialist with the Cardiovascular Credentialing International (CCI) or a Registered Radiologic Technologist [RT(R)] with American Registry of Radiologic Technologists (ARRT) or a Registered Technologist in radiological technology (RTR) with the Canadian Association of Medical Radiation Technologists (CAMRT) with a minimum of five years of experience performing cardiovascular catheterization procedures. A letter from the Medical Director or supervising physician verifying the training, experience and competency in performance and supervision of cardiovascular catheterization procedures is required.

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Comment: If the Technical Manager applying under pathway 1.4.1.3A no longer works in this capacity, it is a recommendation the newly appointed Technical Manager meet one of the following training pathways: 1.4.1.1A or 1.4.1.2A.

1.4.2A Technical Manager Responsibilities

The Technical Manager responsibilities may include, but are not limited to:

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

1.4.2.2A management of pre- and post-procedural care areas;

1.4.2.3A direct participation in the observation and care of patients undergoing cardiovascular catheterization procedures;

1.4.2.4A application of institutional guidelines for patient monitoring, medication administration, procedural sedation and patient safety;

1.4.2.5A managing staff competencies and proficiency in performing tasks required before, during and after the procedure;

1.4.2.6A the delegation, when necessary, of specific responsibilities to the technical and/or nursing staff and/or ancillary staff;

1.4.2.7A verification of documentation of proper training and, at least annually, assessment of the competence of technical and/or nursing staff and/or any ancillary staff who report to the Technical Manager; and

1.4.2.8A demonstrate familiarity and proficiency with the setup and operation of all equipment associated with the cardiovascular catheterization procedures performed in the facility.

(See Guidelines on Page 20 for further recommendations.)

1.4.3A Continuing Education (CE) Requirements

1.4.3.1A The Technical Manager must obtain at least 15 hours of accredited CE relevant to acquired and/or congenital heart disease that includes, but is not limited to, content that is directly related to the performance of cardiovascular catheterization procedures and/or acquired and/or congenital heart disease and/or coronary artery disease and/or patient management every three years.

Comment: Radiation safety training must be part of the CE and not be less than one hour of the 15 hours required (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CE requirement.).

1.4.3.2A All CE hours must be approved (i.e., Recognized Continuing Education Evaluation Mechanism [RECEEM], Cardiovascular Credentialing International [CCI]-Cardiovascular CEU, Alliance of Cardiovascular Professionals [ACVP]-CEU, 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 Manager has successfully attained an appropriate technical credential [RCIS, RT (CI) or RT (CV)] within the three years, prior to the application date, the CE requirement hours will be considered fulfilled.

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

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STANDARD – Nursing Staff

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

1.5.1A Nurse(s) Required Training and Experience

1.5.1.1A The nurse(s) must be licensed and meet at least one of the following criteria:

i. Registered Nurse (RN);
ii. Advanced Practice Nurse (APRN);
iii. advanced health care degree or Bachelor of Science in nursing (BSN) preferred; or
iv. certification in interventional nursing specialty such as Cardiac Nurse Practitioner (NP-C), Cardiovascular Clinical Nurse Specialist (CNS), Cardiac Vascular Nursing (CVRN), Certified Radiology Nurse (CRN).
v. In addition to the credential of RN: Registered Cardiovascular Invasive Specialist (RCIS) with the Cardiovascular Credentialing International (CCI).

1.5.1.2A At least six months of critical care and/or emergency room and/or cardiovascular catheterization nursing is recommended.

1.5.1.3A For adult cardiovascular catheterization:

i. Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) certification are required.

1.5.1.4A For pediatric cardiovascular catheterization:

i. Basic Life Support (BLS) and Pediatric Advanced Life Support (PALS) are required.

1.5.2A Nurse(s) Responsibilities

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

1.5.2.1A reporting to the Nurse Manager and/or Technical Manager;

1.5.2.2A administering and monitoring moderate sedation;

1.5.2.3A performing cardiovascular assessment;

1.5.2.4A knowing relevant radiation safety;

1.5.2.5A monitoring and assessing clinical status of patient;

1.5.2.6A cardiovascular and hemodynamic monitoring and management;

1.5.2.7A monitoring, assessing and management of emergency care to include Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) in facilities performing pediatric cardiovascular catheterization procedures;

1.5.2.8A advising patient care team and treating patient appropriately; and

1.5.2.9A demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the cardiovascular catheterization procedures performed in the facility.

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(See Guidelines on Page 20 for further recommendations.)

1.5.3A Continuing Education (CE) Requirements

1.5.3.1A The cardiovascular catheterization nursing staff must obtain at least 15 hours of accredited CE relevant to acquired and/or congenital heart disease that includes, but is not limited to, content that is directly related to the performance of cardiovascular catheterization procedures and/or acquired and/or congenital heart disease and/or coronary artery disease and/or cardiovascular 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 (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CE requirement.).

1.5.3.2A All CE hours must be American Nurses Credentialing Center (ANCC) approved and/or obtain appropriate CE, Cardiovascular Credentialing International [CCI]-Cardiovascular CEU, Alliance of Cardiovascular Professionals [ACVP]-CEU, American Registry of Radiologic Technologists [ARRT]-Category A, American Society of Radiologic Technologists (ASRT), American Medical Association [AMA]. For nursing staff who administer sedation; at least one contact hour in moderate sedation is required annually.

Comment: If the nursing staff member has successfully attained an appropriate specialty certification (NP-C, CNS, CVRN, CRN or RCIS) 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.

STANDARD – Technical Staff

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

1.6.1A Technologist(s) Required Training and Experience

The technologist(s) must be licensed (where applicable) and meet one or more of the following criteria:

1.6.1.1A A registered specialist with the Cardiovascular Credentialing International (CCI) meeting the following criteria:

i. Registered Cardiovascular Invasive Specialist (RCIS).

1.6.1.2A A registered radiologic technologist with the American Registry of Radiologic Technologists (ARRT) meeting one or more of the following criteria:

i. Cardiovascular-Interventional Radiography RT (CV);
ii. Cardiac-Interventional Radiography RT (CI).

1.6.1.3A A registered specialist with the Cardiovascular Credentialing International (CCI) or a Registered Radiologic Technologist [RT(R)] with American Registry of Radiologic Technologists (ARRT) or a Registered Technologist in Radiological Technology (RTR) with the Canadian Association of Medical Radiation Technologists (CAMRT) with a minimum of one year of full-time equivalent experience as a cardiovascular catheterization technologist/specialist under the direct supervision of personnel meeting pathway 1.6.1.1A or 1.6.1.2A as indicated above. A clinical rotation in interventional, cardiology or invasive procedures as part of their educational program may be counted for up to six months of clinical experience.

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1.6.1.4A An allied professional with a minimum of one year of full-time equivalent experience performing cardiovascular catheterization procedures. A letter from the Medical Director or supervising physician verifying the training, experience and competency in performance and supervision of cardiovascular catheterization procedures is required.

1.6.1.5A Completion of 12 months full-time (35 hours/week) cardiovascular catheterization experience assisting in cardiovascular catheterization procedures plus one of the following:

i. completion of a formal two-year program in another allied health profession;

ii. completion of a bachelor's degree unrelated to a Commission on Accreditation of Allied Health Education Programs (CAAHEP), Joint Review Committee on Education in Radiologic Technology (JRCERT), Accrediting Bureau of Health Education Schools (ABHES) or Canadian Medical Association (CMA) accredited program or bachelor's degree in cardiovascular technology, cardiovascular catheterization or minor in some aspect of cardiovascular technology, which is unrelated to a CAAHEP, JRCERT, ABHES or CMA accredited program.

1.6.2A <u>Cardiovascular Catheterization Technologist(s) Responsibilities</u>

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

1.6.2.1A reporting to the Technical Manager and/or Nurse Manager;

1.6.2.2A reviewing and/or recording pertinent patient history and supporting clinical data;

1.6.2.3A obtaining a record of anatomical, pathological and/or physiological data for interpretation by the physician;

1.6.2.4A positioning of the patient, selection of radiation exposure parameters, imaging of the patient and archiving of the images;

1.6.2.5A maintaining a high degree of awareness of all radiation and patient safety issues involved with any invasive procedure;

1.6.2.6A demonstrating a thorough understanding and working knowledge of normal and abnormal anatomy, physiology, radiation safety, interventional supplies and equipment operation;

1.6.2.7A recognizing and resolving equipment problems and discrepancies, anticipating patient needs and concerns and communicating the appropriate care needed;

1.6.2.8A using professional judgment and critical thinking when assisting procedures;

1.6.2.9A scrubbing in and assisting the physician in the procedure when necessary;

1.6.2.10A circulating within the procedure room and procuring equipment needed for any given procedure;

1.6.2.11A performing other procedures and duties, as assigned;

1.6.2.12A familiar with equipment and able to troubleshoot;

1.6.2.13A certified in Basic Life Support (BLS);

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1.6.2.14A certification in Advanced Cardiac Life Support (ACLS) is recommended;

1.6.2.15A for pediatric cardiovascular catheterization:

i. certified in Basic Life Support (BLS);
ii. certification in Pediatric Advanced Life Support (PALS) is recommended.

1.6.2.16A demonstrate familiarity and proficiency with the setup and operation of all equipment associated with the cardiovascular catheterization procedures performed in the facility.

(See Guidelines on Page 20 for further recommendations.)

1.6.3A Continuing Education (CE) Requirements

1.6.3.1A The technologist staff must obtain at least 15 hours of accredited CE relevant to acquired and/or congenital heart disease that includes, but is not limited to, content that is directly related to the performance of cardiovascular catheterization procedures and/or acquired and/or congenital heart disease and/or coronary artery disease 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 (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CE requirement.).

1.6.3.2A All CE hours must be approved (i.e., Recognized Continuing Education Evaluation Mechanism [RECEEM], Cardiovascular Credentialing International [CCI]-Cardiovascular CEU, Alliance of Cardiovascular Professionals [ACVP]-CEU, American Registry of Radiologic Technologists [ARRT]-Category A, American Society of Radiologic Technologists [ASRT], American Medical Association [AMA], American Nurses Credentialing Center [ANCC]).

Comment: If the cardiovascular catheterization technologist staff member has successfully attained an appropriate technical credential [RCIS, RT(CI) or RT(CV)] 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.

STANDARD – Advanced Practice Providers

1.7A An advanced practice provider(s) works under the direction of the Medical Director or medical staff member who is listed in the application. The advanced practice provider must be a licensed professional who possesses knowledge in the treatment and performance of cardiovascular catheterization procedures and meets the required certification and experience qualifications as outlined in this document and the required certification and experience qualifications determined by local, state and/or federal regulations within the scope of practice of an advanced practice provider.

1.7.1A Advanced Practice Provider Required Training and Experience:

1.7.1.1A The advanced practice provider(s) must be licensed and meet one of the following criteria for required certification and experience:

i. Physician Assistant (PA);
ii. Doctor of Nursing Practice (DNP);
iii. Cardiac Nurse Practitioner (NP-C); or
iv. Nurse Practitioner (NP).

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1.7.1.2A The advanced practice provider must perform, under the supervision of a qualified physician, evaluation of the minimum suggested volume of patients in the previous three years including obtaining a history, performing a physical examination and making medical decisions including the assessment of pertinent diagnostic studies and forming a treatment plan.

i. If assisting adult diagnostic catheterization procedures, supervised participation in the active care of a minimum of 50 cases over the previous three years is suggested (but not required) and must be documented, if claimed.

ii. If assisting percutaneous coronary intervention (PCI) procedures, supervised participation in the active care of a minimum of 50 cases over the previous three years is suggested (but not required) and must be documented, if claimed.

iii. If assisting procedures for valve interventions, supervised participation in the active care of a minimum of 50 cases over the previous three years is suggested (but not required) and must be documented, if claimed.

iv. If assisting procedures for structural heart interventions, supervised participation in the active care of a minimum of 50 cases over the previous three years is suggested (but not required) and must be documented, if claimed.

v. If assisting complex Adult Congenital Heart Disease (ACHD) procedures, supervised participation in the active care of a minimum of 50 cases over the previous three years is suggested (but not required) and must be documented, if claimed.

vi. If assisting pediatric cardiovascular catheterization procedures, supervised participation in the active care of a minimum of 50 cases over the previous three years is suggested (but not required) and must be documented, if claimed.

Comment: Active care means direct care of a patient that would include, at a minimum, gathering a history, performing a physical examination, assessing pertinent diagnostic studies, forming and carrying out a treatment plan and assisting in the performance of the procedure(s) if indicated, as well as documentation of patient outcomes.

1.7.2A <u>Advanced Practice Provider Responsibilities</u>:

1.7.2.1A Advanced practice provider responsibilities may include, but are not limited to:

i. participation in cardiovascular catheterization safety practices including, but not limited to, safe use of equipment and review of patient outcomes and complications;

ii. knowledge and maintenance of sterile technique;

iii. knowledge regarding compression techniques and bandaging;

iv. administering and monitoring moderate sedation;

v. performing cardiovascular assessment;

vi. knowing relevant radiation safety;

vii. monitoring and assessing clinical status of patient;

viii. cardiovascular and hemodynamic monitoring and management;

ix. monitoring, assessing and management of emergency care to include, Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) in facilities performing pediatric cardiovascular catheterization procedures;

x. advising patient care team and treating patient appropriately;

xi. post-procedure discharge instructions;

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xii. patient education;

xiii. assisting a staff physician with image-guided cardiovascular catheterization procedures (when required);

xiv. performing other procedures and duties, as assigned; and

xv. demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the cardiovascular catheterization procedures performed in the facility.

(See Guidelines on Page 20 for further recommendations.)

1.7.3A Provisional Advanced Practice Providers:

1.7.3.1A The Medical Director may appoint a qualified advanced practice provider(s) as provisional staff who meets all of the above criteria with the exception of the direct participation in the active cardiovascular catheterization procedure case volumes as outlined. The Medical Director will be responsible for review of the provisional advanced practice provider including biannual review of the case log including outcomes. The provisional advanced practice provider must attain full advanced practice provider status within three years.

1.7.4A Continuing Education (CE) Requirements:

1.7.4.1A The advanced practice provider must obtain a minimum of 15 credit hours or dedicated CE for Advanced Practice Providers relevant to acquired and/or congenital heart disease that includes, but is not limited to, content that is directly related to the performance of cardiovascular catheterization procedures and/or acquired and/or congenital heart disease and/or coronary artery disease and/or cardiovascular 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 (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CE requirement.).

Comment: If the advanced practice provider has completed formal training and successfully attained an appropriate advanced practice provider credential within the three years, prior to the application date, the CE requirement hours will be considered fulfilled. For those who are appropriately credentialed and completed training prior to three years of the application date, the CE requirement hours will be considered fulfilled if the advanced practice provider has successfully attained a technical credential (i.e., RCIS).

1.7.4.2A All CE hours must be approved (i.e., Recognized Continuing Education Evaluation Mechanism [RECEEM], Cardiovascular Credentialing International [CCI]-Cardiovascular CEU, Society of Interventional Cardiovascular Professionals [SICP]-CEU, American Registry of Radiologic Technologists [ARRT]-Category A, American Society of Radiologic Technologists [ASRT], American Medical Association [AMA], American Nurses Credentialing Center [ANCC]).

1.7.4.3A Documentation of CE credits 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 Director or Nurse Manager or Technical Manager. The specific needs of a facility must be determined by an evaluation of the types and volumes of procedures as well as facility configuration.

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

1.8.1.1A advance practice nurses (APRN);

1.8.1.2A clinical pharmacist;

1.8.1.3A technical assistants;

1.8.1.4A clerical and administrative assistants;

1.8.1.5A computer support staff; or

1.8.1.6A 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 their ancillary personnel appropriate to the assigned duties.

STANDARD – Anesthesia Personnel

1.9A The facility must ensure that adequately trained and experienced anesthesia personnel are available to perform safe and effective patient care appropriate for the level of service as designated by the Medical 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.

1.9.1A Anesthesia personnel may consist of, but are not limited to:

1.9.1.1A Licensed physician board certified by the American Board of Anesthesiology (ABA)

1.9.1.2A Certified Registered Nurse Anesthetist (CRNA)

1.9.2A Anesthesia assistants are permitted when under the direct supervision of a board-certified anesthesiologist or a CRNA.

STANDARD – Medical Physicist

1.10A A qualified medical physicist must be appointed for the facility and meet the following qualifications:

1.10.1A <u>Medical Physicist Required Training and Experience</u>

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

1.10.1.1A Board certification by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or the Canadian College of Medical Physics (CCMP) in a discipline that includes diagnostic imaging is recommended.

1.10.1.2A A physicist who has passed Part 2 of the ABR examination in a discipline of medical physics that includes diagnostic imaging is acceptable. Full certification by a recognized board as outlined above is required prior to the next accreditation cycle.

1.10.1.3A Licensed or certified in accordance with state and local regulations. Full certification by a recognized board as outlined above is required prior to the next accreditation cycle. Individuals listed in the National QMP Registry maintained by the Conference of Radiation Control Program Directors for a subspecialty of medical physics in diagnostic imaging are acceptable.

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1.10.2A Medical Physicist Responsibilities

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

1.10.2.1A perform initial and annual surveys for equipment performance evaluation including:

i. radiation output measurements;
ii. system quality control tests;
iii. image quality performance measurements;
iv. analyze all data with appropriate recommendations;
v. appropriate shielding of rooms and areas of the room considered protected from radiation; and
vi. operation of collimators.

1.10.2.2A provide a written summary of all assessment and evaluations performed;

1.10.2.3A provide guidance for any patient and/or staff dosimetry issues;

1.10.2.4A provide radiation training for facility physicians and staff as required;

1.10.2.5A Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist in the collection of data under the direct supervision of the medical physicist. The medical physicist must review and approve all such data. The medical physicist remains personally responsible for the performance quality of the assigned tasks.

1.10.2.6A A process must be in place for the management, review, report and documentation, by the radiation safety committee/medical physicist/radiation safety officer, of the following:

i. staff radiation badges;
ii. radiation protective garments and accessories;
- vests;
- skirts;
- aprons;
- thyroid shields;
- gloves;
- protective eyewear;
- other.

iii. patient radiation exposure;
iv. other.

Comment: All radiation protective garments and accessories must be examined annually with use of fluoroscopy and/or radiography for cracks, tears, detachment or other form(s) of damage.

Comment: All radiation protective garments and accessories must be routinely cleaned according to hospital infection control policy(s) and manufacturer recommendation(s).

1.10.2.7A It is recommended that the physicist observe at least one (cardiovascular catheterization) procedure with diagnostic imaging including fluoroscopy per year.

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1.10.3A Continuing Education (CE) Requirements

1.10.3.1A The medical physicist must obtain at least 15 credits hours of CE approved by the Commission on Accreditation of Medical Physics Education Program (CAMPEP) in diagnostic imaging including fluoroscopy, every three years.

i. The 15 CAMPEP hours should include education in radiation dosimetry, radiation protection and equipment performance related to the use of fluoroscopy. The medical physicist should regularly perform a sufficient number of radiation measurements, dosimetry calculations and equipment performance evaluations of fluoroscopic equipment to maintain competence in the performance of these activities.

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.

1.10.3.2A Documentation of CAMPEP credits must be kept on file and available for inspection.

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Section 1A: Personnel and Supervision
Guidelines

1.1.2A, 1.2.2A, 1.3.2A, 1.4.2A, 1.5.2A, 1.6.2A and 1.7.2A	*Personnel performing and/or assisting cardiovascular catheterization procedures should comply with training requirements as listed in the SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Catheterization Laboratory[24],2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update[6] and ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures.[7]*

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Section 2A: Facility

STANDARD – Examination Areas

2.1A Adequate facilities must be provided for all operations of the facility so that patient comfort, safety, dignity and privacy are ensured as well as staff comfort and safety. Procedure areas must have sufficient space, be well maintained and clean. There should be adequate space for the cardiovascular catheterization personnel to freely access the patient and for all staff to maintain the sterile field. Physical space requirements include, but are not limited to:

(See Guidelines on Page 31 for further recommendations.)

2.1.1A waiting, reception and patient/staff bathrooms;

2.1.2A patient education, consultation and examination areas;

2.1.3A readily accessible handwashing/sanitation for staff;

2.1.4A performance of pre-test/post-procedures within appropriate proximity of the procedure area including adequate space for performing resuscitation in case of emergency;

2.1.5A emergency cardiovascular surgical support must be immediately available in case of life-threatening procedural complications;

Comment: Refer to Part B for procedural requirements requiring emergency cardiovascular surgical support and protocol for the transfer of patients to a tertiary facility in the event of an emergency.

Comment: Cardiovascular catheterization procedures on pediatric patients, as well as patients of any age with complex congenital heart defects, should only be performed at centers with experienced cardiovascular surgical staff and the proper equipment to provide back-up for emergencies.[13]

Comment: Centers performing pediatric cardiovascular catheterization should have an on-site pediatric intensive care unit and an on-site pediatric cardiac surgery program, in addition to a pediatric cardiac anesthesia service. The pediatric cardiovascular catheterization laboratory (PCCL) should have access to rescue ECMO, in addition to standard resuscitation methods and technologies.[6,20,32]

Comment: Centers performing adult congenital heart defect (ACHD) cardiovascular catheterization should have an on-site cardiac intensive care unit with an ACHD consultation service, an on-site ACHD surgical program, and a cardiac anesthesia service. The ACHD catheterization laboratory should have access to rescue ECMO, in addition to standard resuscitation methods and technologies.[6,20,32]

2.1.6A adequate space, facility configuration and doorways for the emergency transport of patients from patient care areas and for emergency exit of staff;

2.1.7A the following procedure room type/area must comply with all Standards listed above (2.1.1A through 2.1.6A) and have or meet, but not limited to, the following[6]:

2.1.7.1A Dedicated Cardiovascular Catheterization Suites: Cardiovascular catheterization procedure rooms that may additionally offer, intracardiac echocardiography (ICE), transesophageal echocardiography (TEE), and use of robotics, which must provide for/include, but not limited to[6,13,14,15,16]:

i. positive airflow;

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ii. high flow oxygen and vacuum for suctioning;

iii. medical gas availability;

iv. substerile scrub area;

v. patient post-procedural care area(s);

vi. 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.

vii. General room lighting: Overhead and task lighting must be adequate to perform cardiovascular catheterization procedures and for clinical evaluation and treatment of the patient. 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.

viii. Room power: The facility must have a plan that outlines the response to unexpected power loss or computer function, such as movement of the patient to another similarly capable procedure room in the immediate vicinity.

- When normal power is not available, emergency power should be capable of providing a minimum of 10 minutes of fluoroscopy, and at least one hour of backup power for the computers, monitoring equipment and ancillary equipment.
- For systems ordered after July 2011, there should be sufficient emergency power supply to run fluoroscopy for a duration of one hour and to run the remainder of the x-ray system components including lighting, for a minimum of 24 hours.
- Utilization of emergency power must be visible by the operator at the normal working position.
- An uninterruptible power supply for all computer equipment is required.
- X-ray equipment and computers should not require rebooting during transition between normal and emergency power or during power line instabilities.

ix. cardiovascular catheterization specific equipment:

- contrast injectors.

x. defibrillator;

xi. electrocardiogram and hemodynamic monitoring equipment capabilities as described in Standard 2.4.4A;

xii. radiolucent table to include, but not limited to:

- height adjustable;
- support more than 159kg/350 lbs.;
- longitudinal and lateral displacement; and
- length and width appropriate to accommodate the patient population being treated (e.g., pediatric, adult, bariatric).

xiii. non-invasive blood pressure monitor;

xiv. supplies specific to the procedure(s) being performed;

xv. emergency equipment and supplies as required by Standard 2.4.3A;

xvi. adequate space must be provided to facilitate the use of emergency support equipment to include, but not limited to:

- cardiopulmonary bypass;
- extracorporeal membrane oxygenation;

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- intra-aortic balloon pump;
- Impella;
- other.

xvii. a fixed radiographic imaging system with flat-panel fluoroscopy offering cardiovascular catheterization laboratory-quality imaging;

xviii. radiation shielded barriers that meet state and federal requirements; and

xix. fluoroscopy equipment must comply with requirements set by the Standards (refer to Appendix A).

Comment: A bi-plane unit is recommended for procedures involving patients with congenital heart disease.

2.1.7.2A Combined Hybrid Laboratories/Hybrid Surgical Suites: These are operating surgical rooms offering cardiovascular catheterization procedures such as; valve interventions, structural heart interventions, complex ACHD and pediatric interventions, which must provide for/include, but not limited to[6,20,21,22,23]:

i. positive airflow;

ii. high flow oxygen and vacuum for suctioning;

iii. medical gas availability:

- medical air;
- nitrogen;
- nitrous oxide;
- oxygen.

iv. waste gas lines;

v. substerile scrub area;

vi. patient post-procedural care area(s);

vii. 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.

viii. General room lighting: Overhead and task lighting must be adequate to perform cardiovascular catheterization procedures and for clinical evaluation and treatment of the patient. 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.

ix. Room power: The facility must have a plan that outlines the response to unexpected power loss or computer function, such as movement of the patient to another similarly capable procedure room in the immediate vicinity.

- When normal power is not available, emergency power should be capable of providing a minimum of 10 minutes of fluoroscopy, and at least one hour of backup power for the computers, monitoring equipment and ancillary equipment.
- For systems ordered after July 2011, there should be sufficient emergency power supply to run fluoroscopy for a duration of one hour and to run the remainder of the x-ray system components including lighting, for a minimum of 24 hours.
- Utilization of emergency power must be visible by the operator at the normal working position.
- An uninterruptible power supply for all computer equipment is required.

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- X-ray equipment and computers should not require rebooting during transition between normal and emergency power or during power line instabilities.

x. cardiovascular catheterization-specific equipment:
   - contrast injectors.

xi. defibrillator;

xii. electrocardiogram and hemodynamic monitoring equipment capabilities as described in Standard 2.4.4A;

xiii. radiolucent table to include, but not limited to:
   - height adjustable;
   - support more than 159kg/350 lbs.;
   - longitudinal and lateral displacement; and
   - length and width appropriate to accommodate the patient population being treated (e.g., pediatric, adult, bariatric).

xiv. non-invasive blood pressure monitor;

xv. supplies specific to the procedure(s) being performed;

xvi. emergency equipment and supplies as required by Standard 2.4.3A;

xvii. snares and other retrieval devices;

xviii. adequate space must be provided to facilitate the use of emergency support equipment to include, but not limited to:
   - cardiopulmonary bypass;
   - extracorporeal membrane oxygenation;
   - intra-aortic balloon pump;
   - other.

xix. a fixed radiographic imaging system with flat-panel fluoroscopy offering cardiovascular catheterization laboratory-quality imaging;

xx. radiation shielded barriers that meet state and federal requirements;

xxi. fluoroscopy equipment must comply with requirements set by Standards (refer to Appendix A).

Comment: A bi-plane unit is recommended for procedures involving patients with congenital heart disease.

(See Guidelines on Page 31 for further recommendations.)

2.1.7.3A Pediatric Cardiovascular Catheterization Suites: Procedure rooms performing pediatric cardiovascular catheterization procedures have similar requirements as that of rooms detailed in Standards 2.1.7.2A and 2.1.7.3A with the exception of the following requirements, which must include, but not limited to[1,6]:

i. pediatric resuscitation equipment;

ii. pediatric appropriate medication dosages;

iii. inventory of pediatric catheters;

iv. inventory of pediatric basic supplies;

v. fluoroscopy equipment must comply with requirements set by the Standards (refer to Appendix A);

vi. fluoroscopy equipment must allow for digital acquisition or saved fluoroscopy.

Comment: Centers performing pediatric cardiovascular catheterization should have an on-site pediatric intensive care unit and an on-site pediatric cardiac surgery program, in addition to a pediatric cardiac anesthesia service. The pediatric

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cardiovascular catheterization laboratory (PCCL) should have access to rescue ECMO, in addition to standard resuscitation methods and technologies.[6,20,32]

Comment: Centers performing adult congenital heart disease (ACHD) cardiovascular catheterization should have an on-site cardiac intensive care unit with an ACHD consultation service, an on-site ACHD surgical program, and a cardiac anesthesia service. The ACHD catheterization laboratory should have access to rescue ECMO, in addition to standard resuscitation methods and technologies.[6,20,32]

Comment: Facilities offering cardiovascular catheterization procedures and personnel participating in these programs must have a protocol for emergency response when the need arises. There must be a mechanism in place to activate a rapid operating room response team that is capable of performing emergency surgery. This "disaster plan" should be regularly tested on a scheduled basis so that each member of the team knows exactly what to do and how to accomplish their role. This plan must be recorded as part of the written standard operating procedure of every extraction laboratory or operating room.

(See Guidelines on Page 31 for further recommendations.)

2.1.8A The control room/area must have or meet:

2.1.8.1A if the procedure room is contiguous with the control room, a leaded wall with a large leaded viewing window;

2.1.8.2A a full duplex intercom system;

2.1.8.3A desk space adequate to accommodate:

i. fluoroscopy monitors; and
ii. a recording system.

(See Guidelines on Page 31 for further recommendations.)

2.1.9A The substerile entrance(s) must have or meet:

2.1.9.1A entrance with dedicated or shared between adjacent procedure rooms;

2.1.9.2A entrance for patient transport from the prep area to the cardiovascular catheterization laboratory(s); and

2.1.9.3A egress that connects to hallways leading to the hospital wards and other areas.

STANDARD – Interpretation Areas

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

(See Guidelines on Page 31 for further recommendations.)

STANDARD – Storage Space

2.3A Adequate space must be provided for:

2.3.1A the storage must ensure confidentiality of data and be safe from fire/flood;

2.3.2A patient records, reports and digital data storage areas;

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2.3.3A administration records and support areas; and

2.3.4A equipment/supply storage areas.

(See Guidelines on Page 31 for further recommendations.)

STANDARD – Equipment and Instrumentation

2.4A Equipment and instrumentation used in the performance of cardiovascular catheterization procedures must be appropriate, in good working condition and should substantially comply with the International Electrotechnical Commission (IEC) 60601-2-43 interventional standard.

(See Guidelines on Page 31 for further recommendations.)

2.4.1A All equipment and instrumentation must be routinely inspected for safety and proper functionality and records of the inspections kept on file. Equipment and instrumentation must include at a minimum the following[17,18,45]:

(See Guidelines on Page 31 for further recommendations.)

2.4.1.1A a fixed (recommended) or portable, single or biplane (recommended) cine angiography system that must meet the following specifications;

2.4.1.2A digital subtracted cine angiography imaging capable of cine frame rates from 15 to 60 frames per second;

2.4.1.3A when applicable, digital subtraction angiography imaging of at least three frames per second, with the ability to do program change of rate during the image acquisition run;

2.4.1.4A when applicable, high quality, subtracted digital radiographs;

2.4.1.5A road-mapping with ability to refer back to an unsubtracted live image;

2.4.1.6A last image hold;

2.4.1.7A pulsed fluoroscopy;

2.4.1.8A dose measurement capability;

2.4.1.9A Digital Imaging and Communications in Medicine (DICOM) compatible digital image storage with capability of storing uncompressed images on portable format without loss of image resolution;

2.4.1.10A ability to display and review prior relevant images during the procedure;

2.4.1.11A minimum 9-inch field of view (FoV) imaging intensifier at a Source Image Receptor Distance (SID) of 30 inches;

2.4.1.12A minimum spatial resolution of matrix of 512 x 512;

2.4.1.13A for pediatric procedures, multiple focal spot sizes to accommodate the patient population imaged at the facility;

2.4.1.14A image monitor performance using the Society of Motion Picture and Television Engineers (SMPTE) pattern;

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2.4.1.15A for equipment installed before 2006 that does not display cumulative dose and or dose area product (DAP), documentation of fluoroscopy time and the number of images per procedure is acceptable; and

2.4.1.16A radiation use must be consistent with the "as low as reasonably achievable" principle or ALARA radiation safety guidelines.

2.4.2A All equipment and instrumentation must be routinely inspected for safety and proper functionality and records of the inspections kept on file.

2.4.3A Emergency equipment and supplies (response cart or kit) must include, but not limited to:

2.4.3.1A oxygen/suction;

2.4.3.2A biphasic external defibrillator with a backup defibrillator immediately accessible;

2.4.3.3A external pacemaker equipment;

2.4.3.4A when applicable, intra-aortic balloon pump (IABP);

2.4.3.5A when applicable, cardiopulmonary bypass (CPB);

2.4.3.6A when applicable, extracorporeal membrane oxygenation (ECMO);

2.4.3.7A emergency trays for pericardiocentesis;

Comment: For interventional procedures, there must be a process in place for immediate access to thoracotomy and sternotomy trays.

2.4.3.8A standard Advance Cardiac Life Support (ACLS) medications (including a master list with verification of expiration date) to include, but not limited to:

i. epinephrine;
ii. atropine;
iii. dopamine;
iv. vasopressin;
v. adenosine;
vi. amiodarone;
vii. magnesium sulfate;
viii. calcium chloride;
ix. potassium chloride;
x. sodium bicarbonate; and
xi. sedative reversal agents:
- flumazenil;
- naloxone.

2.4.3.9A endotracheal intubation equipment to include:

i. sedative(s);
ii. paralytic agent(s); and
iii. anesthetic agent.

2.4.3.10A resuscitator bag and mask;

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2.4.3.11A non-rebreather mask;

2.4.3.12A arterial blood gas kits;

2.4.3.13A separate monitoring system for ECG and hemodynamics to include:

i. pressure transducer; and
ii. end-tidal carbon dioxide monitor.

2.4.4A Monitoring equipment must be available to perform:

2.4.4.1A intravascular pressure;

2.4.4.2A non-invasive blood pressure;

2.4.4.3A pulse oximetry;

2.4.4.4A activated coagulation time (ACT) analyzer;

2.4.4.5A electrocardiogram (ECG);

i. 12-lead surface ECG.

2.4.4.6A capnography (CO2) monitoring is recommended for use with moderate sedation.

2.4.5A Procedure table(s) must be radiolucent, motorized and have the following capabilities:

2.4.5.1A height adjustable;

2.4.5.2A support more than 159kg/350 lbs.;

2.4.5.3A longitudinal and lateral displacement; and

2.4.5.4A length and width appropriate to accommodate the patient population being treated (e.g., pediatric, adult, bariatric).

2.4.6A Additional systems and applications may be used during the course of performing a cardiovascular catheterization procedure:

2.4.6.1A Intracardiac echocardiography (ICE) systems using a linear phased array transducer that produces a 90-degree image longitudinal to the catheter and/or a rotational transducer to display a 360-degree image perpendicular to the catheter.

(See Guidelines on Page 31 for further recommendations.)

2.4.6.2A robotic navigation systems; and

2.4.6.3A transthoracic echocardiography (TTE) and/or transesophageal echocardiography (TEE) (refer to 2.4.7A for additional requirements).

.

(See Guidelines on Page 31 for further recommendations.)

2.4.7A Ultrasound imaging equipment:

2.4.7.1A Must meet the *IAC Standards and Guidelines for Adult and/or Pediatric Echocardiography Accreditation* for equipment and must include:

i. color flow Doppler;

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ii. imaging frequencies appropriate for the structures evaluated;

iii. Doppler frequencies appropriate for the vessel evaluated;

iv. a visual display and capability of permanent recording of the image; and

v. a visual display, audible output and capability for a permanent recording of the Doppler waveform and corresponding image.

2.4.8A Adequate disposable supplies must be immediately available. These include U.S. Food and Drug Administration (FDA) approved catheters, wires, stents, balloons and embolic protection devices. Non-FDA approved devices may also be used as permitted by law.

2.4.9A Ancillary equipment as appropriate (e.g., monitoring equipment, blood coagulation testing equipment, workstations, picture archiving communication system [PACS], radiation protection for personnel [aprons and thyroid shields, portable shield either on wheels or suspended from ceiling]).

STANDARD – Equipment and Instrumentation Quality Control

2.5A There must be a comprehensive Quality Improvement (QI) program to provide a standard of measurement for system performance and the documentation of any variance thereof.

2.5.1A A QI Committee should be appointed to provide oversight to the equipment and instrumentation quality control (QC).

2.6A Fluoroscopic system QC testing must include a comprehensive evaluation of the system components, image performance and radiation output limits as outlined in the FDA Code of Federal Regulations (CFR) Title 21 subchapter J, Parts 1010 and 1020 and applicable FDA guidance documents.[11]

2.7A Image quality requirements, radiation output limits, and other fluoroscopic performance requirements must also comply with the health-code regulations of the state in which the facility is located.

2.8A The site-appointed qualified medical physicist must complete the performance evaluations at equipment installation and annually, unless state regulations require more frequent testing. Equipment performance evaluations are recommended semi-annually to include radiation output measurements, system quality control tests and image quality performance measurements.

2.9A The site-appointed medical physicist must perform a radiation safety survey to ensure that occupational workers and members of the public are shielded according to state regulation. This must be performed prior to installation of each new angiographic imaging system. A documented radiation safety survey of the cardiovascular catheterization suite and adjacent areas that has been accepted by the State Radiation Program fulfills this requirement.

2.10A A radiation safety survey must be performed on all renovated or newly constructed interventional/ cardiovascular catheterization suites and adjacent areas. This must be performed prior to first patient use. This survey must confirm that the levels of radiation protection are in conformance with the State Radiation Program.

2.11A All spaces outside the procedure rooms should provide adequate protection for full time occupancy by non-radiation workers. This recommendation includes the control room.

2.12A Preventive maintenance (PM) on all cardiovascular catheterization equipment listed in Standards 2.4.4.A, 2.4.5A, 2.4.6A, 2.4.7A and 2.4.8A is required according to the manufacturer's recommendations.

2.13A Preventive maintenance (PM) service is recommended periodically per the manufacturers' recommendations for each angiographic system at the facility.

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2.14A Ancillary equipment (e.g., hemodynamic monitoring equipment, blood gas and coagulation testing equipment, workstations, PACS, lead aprons, suction, oxygen lines, etc.) should also be included in a PM program.

2.15A The emergency response cart or kit must be checked at least monthly, with documentation to assure that all expected items are present and the supplies are not expired.

2.16A There must be a process to check inventory of disposable supplies (e.g., catheters, wires, balloons, stents, embolic protection devices, contrast, and portable oxygen tank) on a regular basis to assure that these supplies are readily available during a procedure.

STANDARD – Quality Control Documentation

2.17A All QC results must be documented and reviewed.

2.17.1A Documentation of the physicists' evaluation, preventive maintenance and quality control tests performed, and service records for all angiographic systems and ancillary equipment must be maintained at the facility and available for review. The reports must be signed and dated by the person(s) performing the tests.

2.17.2A Results of all QC tests must be documented, archived and stored on film, in digital format, or on other suitable media according to state requirements (if applicable).

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Section 2A: Facility
Guidelines

2.1A The participation of an ergonomics expert in the planning should be considered as a measure to comply with Occupational Safety and Health Administration standards.

2.1.7A The Guidelines for Design and Construction of Hospitals and Health Care Facilities published by the American Institute of Architects and the Facility Guidelines Institute provide space and functionality standards for cardiovascular catheterization laboratories with a goal to improve work flow in the cardiovascular catheterization environment.

The minimal procedural area of a complete cardiovascular catheterization laboratory (not including control room space) is 350 square feet of clear floor area.

There should be a minimum of 8 feet of clear space between the wall and the edges of each side of the patient table when it is positioned at the isocenter.

Enough clearance at the head of the bed should be allocated for anesthesia equipment on either side and sterile access to jugular vein entry sites, if employed, while allowing for free range of movement of the fluoroscopy C-arm.

Current electrical system regulations for health care facilities should follow Article 517 of the National Electrical Code (NEC) Handbook

The air flow/heating, ventilation, and air conditioning design should comply with the Guidelines for Environmental Infection Control in Health-Care Facilities Recommendations of the Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee document.

Lighting should include an overhead light on an articulating arm, 2 x 2 feet lighting squares to flood the main procedure area, and a dedicated workspace light for the nursing/anesthesia area.

2.1.7A and 2.1.8A The ideal sound/communication system is an always-on, full-duplex, two-way intercom system.

Network cabling and hardware should have a minimum capability of support for gigabit Ethernet speed.

2.1.7.2A Hybrid rooms should be in close proximity to operating room(s) or catheterization suite(s) and located on a clear core or semirestricted corridor where scrubs, hats and masks are required.[6]

2.1.8.3A An additional 45 inches of desk space is suggested for a two-monitor reading station or single-monitor workstation.

2.2A and 2.3A Electronic storage of cardiovascular catheterization data should be Health Insurance Portability and Accountability Act (HIPAA) compliant. Data should be maintained for at least the minimum duration as determined by each state.

2.4A Integrated data display systems provide flexibility and efficiency in data display; it is advisable to have separate backup monitors in case of failure.

2.4.1A It is important to achieve the lowest possible noise signal with all recording systems.

2.4.6.1A Intracardiac Echocardiography (ICE) may be useful as an adjunctive imaging modality during complex procedures.

2.4.6.3A Transthoracic echocardiography and transesophageal echocardiography should be readily available for emergency use and for adjunctive imaging in selected cases.

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Section 3A: Administrative

STANDARD – Patient Confidentiality

3.1A 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

3.2A 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

3.3A 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.

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Section 3A: Administrative
Guidelines

Sample documents are available for each of the required policies listed in Section 3A on the IAC Cardiovascular Catheterization website at intersocietal.org/cath/seeking/sample_documents.htm.

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Part B: Process

Section 1B: Procedures and Protocols

STANDARD – Procedure Overview

1.1B The cardiovascular catheterization 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.

(See Guidelines on Pages 64-68 for further recommendations.)

1.1.1B The facility must assure that appropriate staff members with BLS, ACLS and PALS 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.

(See Guidelines on Pages 64-68 for further recommendations.)

1.1.3B All staff must observe adherence to:

1.1.3.1B standardized uniformly applied universal precautions in every aspect of patient care;

1.1.3.2B national patient safety goals (e.g., medication safety);

1.1.3.3B infection control measures consistent with CDC and OSHA guidelines.

1.1.4B When in the presence of ionizing radiation, all staff must observe proper radiation safety techniques to include, but not limited to: wearing radiation protective garments; thyroid shield, vest with skirt or full-length apron or full-length jacket. Garments must meet a lead equivalent of 0.5mm with a weight per unit area of 7 kg/m2. Alternatively, staff may use a floor-mounted/portable radiation protection cabin and a ceiling- or gantry-mounted suspended radiation protection system. However, all staff using these systems must be able to completely fit behind these lead barriers whenever radiation is being used.

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: diagnostic catheters, therapeutic catheters and implantable devices.

1.2.2B Appropriate pharmacologic agents must be readily available for use during the procedure. The facility must have policy in place for the oversight of distribution for pharmacologic agents by a clinical pharmacist.

1.2.3B Proper identification of the patient and planned procedure 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.[19] This must be performed immediately before the initiation of the procedure when all key personnel are present.

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All procedures, performed with or without moderate sedation and/or with or without general anesthesia, must be explained to the patient and/or the parents or guardians of those unable to give informed consent. Consent must be obtained in a manner consistent with the rules and regulations required by the hospital or facility. During the use of moderate sedation and/or general anesthesia there must be methods in place to assess the patient's level of consciousness pre-procedure and throughout the procedure. Written policies must exist for the use of conscious sedation including, but not limited to:

1.2.3.1B type of sedatives and appropriate dosing; and

1.2.3.2B monitoring during and after the examination.

(See Guidelines on Pages 64-68 for further recommendations.)

1.2.4B A fire safety evaluation must be performed prior to the start of the procedure whenever there is potential for a flammable substance to be used in the presence of oxygen.[26,27,28,28,49] This must be performed immediately before the initiation of the procedure when all key personnel are present.

1.2.5B History and physical examination must be performed within 30 days and should be in the chart and include documentation of relevant laboratory testing, medications, allergies and bleeding disorders.

1.2.6B Cardiovascular assessment, must be documented.

1.2.6.1B Patients undergoing a cardiovascular catheterization procedure will undergo cardiovascular assessment prior to and following the procedure to document pre-procedural status, post-procedural status and evaluate for any procedural complications. Cardiovascular assessment must include, but not limited to:

i. pre-procedure assessment:
- heart rate and rhythm;
- blood pressure;
- symptoms;
- comorbidity(s);
- medications and allergies;
- other.

ii. post-procedure assessment:
- heart rate and rhythm;
- blood pressure;
- symptoms;
- complication(s);
- other.

1.2.7B When applicable, laboratory testing should be carried out and documented in the medical record to include, but not limited to: electrolytes, blood urea nitrogen (BUN), creatinine, complete blood count (CBC), blood type and screen (if indicated, within 30 days of the procedure). Prothrombin time (INR), if taking warfarin and pregnancy test (in females of childbearing age) should be performed within 24 hours of procedure. If pre-procedure laboratory testing is performed outside the facility, the results of that testing must be included inside the facility's medical record (e.g., intake history and physical). Positive blood cultures must also be documented in the facility's medical record and interpreted by the responsible physician.

1.2.7.1B A policy must designate which procedures require type and crossmatch for the availability of blood products.

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1.2.8B When applicable, antithrombotic therapy should be administered prior to the procedure, during the procedure and after the procedure.

1.2.9B For any procedure, to include but not limited to: PCI, valve interventions, septal closure, etc., administration of an appropriate antibiotic within one hour before intervention is required.

1.2.10B Paddle or self-adhesive external defibrillation pads must be available prior to the onset and for the duration of the procedure.

1.2.10.1B When using self-adhesive external defibrillation pads, they must be placed on the patient's chest prior to the onset of the procedure.

1.2.11B The facility must have a process to address procedural complications (refer to Standard 3.1.2C).

1.2.12B The operator must be aware of prior PCI and CABG data and review the associated prior imaging and/or report(s), if available.

1.2.13B The operator must be aware of all device and lead hardware present, including those in use and previously abandoned.

1.2.14B Procedure preparation must also include:

1.2.14.1B intravenous access appropriate for patient size and procedure performed;

1.2.14.2B continuous electrocardiographic monitoring;

1.2.14.3B blood pressure monitoring (invasive or non-invasive); and

1.2.14.4B when applicable, skin prep to allow for emergent pericardiocentesis, thoracotomy, sternotomy and cardio-pulmonary bypass.

(See Guidelines on Pages 64-68 for further recommendations.)

1.3B During the performance of the procedure:

1.3.1B Standard Advance Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) medications must be available, according to Standard 2.4.3.8A.

1.3.2B Physiologic monitoring must include continuous electrocardiographic monitoring:

1.3.2.1B blood pressure monitoring (invasive or non-invasive);

1.3.2.2B pulse oximetry; and

1.3.2.3B capnography may be used (if appropriate).

1.3.3B Intravenous access for administration of fluids and medications must be in place.

1.3.4B Radiation must be monitored during the procedure.[45]

1.3.4.1B Radiation use must be consistent with the "as low as reasonably achievable" principle or ALARA radiation safety guidelines.

1.3.5B Adequate anticoagulation should be monitored with activated clotting time (ACT) throughout the procedure.

1.3.6B Acquisition of representative diagnostic or pre-, intra- and post-intervention angiographic imaging.

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1.3.7B Acquisition of representative pre-, intra- and post intervention ultrasound imaging, when applicable:

1.3.7.1B Ultrasound imaging may include one or more of the following:

i. transthoracic echocardiography (TTE);
ii. transesophageal echocardiography (TEE);
iii. intracardiac echocardiography (ICE); and
iv. intra-vascular ultrasound (IVUS).

1.4B Following the performance of the procedure:

1.4.1B Perform and document post-procedure basic cardiovascular evaluation to assess for new complications prior to moving the patient off the table.

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

1.4.2B Assessment of blood pressure and the status of the puncture site.

1.4.2.1B Blood pressure must be controlled post-procedure according to the facility protocol.

1.4.2.2B The facility must have a protocol in place to address sheath removal and personnel appropriate to manage sheath removal.

1.4.3B 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.

1.4.3.1B Complications may include, but not limited to[7, 19,22]:

i. acute renal failure;
ii. acute stroke/transient ischemic attack (TIA) or other neurologic events;
iii. arrhythmias requiring treatment;
iv. cardiac arrest;
v. cardiac perforation;
vi. cardiac tamponade;
vii. cardiac valve injury;
viii. contrast reaction;
ix. conduction block;
x. coronary perforation;
xi. excess radiation dose;
xii. hematoma;
xiii. hemothorax;
xiv. intracranial hemorrhage;
xv. lead dislodgement;
xvi. myocardial infarction:
- rise and fall of cardiac biomarkers;
- ECG changes with or without symptoms; and
- imaging evidence of regional loss of viable myocardium at rest in the absence of a non-ischemic cause.

xvii. pericardial effusion;
xviii. peripheral embolus;

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xix. pneumothorax;

xx. stent thrombosis;

- other adverse events:
  - stent loss;
  - retained foreign body;
  - guidewire fracture;
  - other.

xxi. sudden cardiogenic shock;

xxii. vascular complications requiring treatment or intervention:

- major drop in hemoglobin (>3.0 g/l) or requirement for blood transfusion;
- major bleeding;
- access site vascular injury;
- retroperitoneal hemorrhage;
- arterial access vessel occlusion or dissection;
- access site infection;
- DVT/pulmonary embolism;
- dissections; pseudoaneurysms;
- arteriovenous (AV) fistula;
- stent loss – peripheral;
- other.

xxiii. other.

(See Guidelines on Pages 64-68 for further recommendations.)

1.4.4B The patient must be moved to an appropriate setting such as a separate periprocedural area, the general cardiology floor, or a cardiac critical care/intensive care/step down unit with the equipment and trained personnel necessary to perform cardiovascular and hemodynamic monitoring and assessment. When appropriate, continuous telemetry should be available for the evaluation of heart rhythm. The environment for post-procedural care should be appropriate for patient age and development. When appropriate, the nursing and physician staff should be experienced in the care of pediatric and congenital cardiovascular catheterization patients.

1.4.5B Document post-procedure cardiovascular assessment within approximately 24 hours and/or prior to discharge.

1.4.6B Document discharge instructions for patient and/or family.

(See Guidelines on Pages 64-68 for further recommendations.)

1.4.7B Radiation usage as recorded by the angiographic system (i.e., fluoro time, DAP, mGy/cm) during the procedure must be documented in the final procedure report as defined in Fluoroscopy: Equipment and Instrumentation and referenced in the NCDR Statement Number 11: Report 168[29] (refer to Appendix B).

STANDARD – Procedure Interpretation and Reports

1.5B Provisions must exist for the timely reporting of examination data.

1.5.1B There must be a policy in place for communicating critical results.

1.5.2B Preliminary reports and/or post-procedural note(s) can only be issued by a physician and/or physician assistant or nurse practitioner under the direction of the interpreting physician. There must be a

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policy in place for communicating any significant changes between the preliminary and final reports.

1.5.3B Routine inpatient cardiovascular catheterization procedures must be interpreted by a qualified physician within 24 hours of completion of the examination. Outpatient studies must be interpreted by the end of the next business day. The final verified (by the interpreting physician) signed report must be completed within 48 hours after interpretation or two business days for outpatient procedures.

1.6B Adult diagnostic catheterization reporting must be standardized in the facility. Complete information regarding all components of the procedure must be documented in the medical record, although the exact format of data reporting may vary among institutions. Generally, reporting is accomplished with a physician-authored procedure or operative note, a nursing or technical record, and an anesthesia or sedation record. In cases where procedural sedation is administered by non-anesthesia nursing staff, the sedation record may be included within the nursing record.

1.6.1B The nursing or technical record must include all technical aspects of the procedure, unless recorded in the anesthesia record, to include but may not be limited to:

1.6.1.1B Demographics:

i. name and/or identifier of the facility;
ii. name and/or identifier of the patient;
iii. date of birth and/or age of the patient;
iv. date of the study;
v. type of study;
vi. name or initials of technical, nursing and ancillary staff participating in the cardiovascular catheterization procedure; and
vii. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

1.6.1.2B Baseline data:

i. height;
ii. weight;
iii. gender;
iv. baseline heart rate, blood pressure prior to the start of the procedure; and
v. allergies.

1.6.1.3B Procedural data, when applicable:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;
v. physician scrub-in time;
vi. percutaneous access time;
vii. activated clotting time(s) (ACT), if applicable;
viii. arterial blood gas, if applicable;
ix. type of sedation (general anesthesia vs. moderate sedation vs. no sedation);
x. medications administered;
- dose; and

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- time given.

xi. vascular access:

- sites;
- sheath size; and
- sheath-in time.

xii. hemodynamic data;

xiii. sheath removal;

xiv. fluoroscopic exposure (list one or more of the following):

- fluoroscopy time;
- radiation dose (i.e., mGy);
- dose-area product.

xv. contrast agent(s), if used, the following must be documented:

- name of contrast(s);
- volume(s) injected; and
- other data, as required.

xvi. diagnostic imaging - imaging to demonstrate adequate opacification of coronary artery segment(s)[30]:

- angiographic projections for optimal visualization of the coronary artery segments.

  Comment: For angiographic projections for optimal visualization of the left and right coronary artery segments.

(See Guidelines on Pages 64-68 for further recommendations.)

xvii. additional imaging and measures, when applicable:

- intravascular ultrasound (IVUS);
- intracardiac echocardiography (ICE);
- transthoracic and/or transesophageal echocardiography;
- method of measuring flow reserve (e.g., IFR, FFR, etc.);
- other imaging and measures, as required.

xviii. other data/information, as required.

Comment: Facilities must have the ability to measure lesion significance by one of the standard accepted flow mediated technologies and applicable staff must be able to demonstrate proficiency in the use of said technology.

1.6.1.4B Post-procedural data:

i. blood pressure;

ii. heart rate;

iii. rhythm;

iv. level of consciousness;

v. oxygenation; and

vi. hemostasis.

1.6.2B The anesthesia record must include all aspects of the procedure relating to anesthesia or sedation, and the patient's response to anesthesia or sedation:

1.6.2.1B Pre-procedural data:

i. height;

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ii. weight;
iii. gender;
iv. anesthesia risk assessment;
v. baseline blood pressure prior to the start of the procedure; and
vi. allergies.

1.6.2.2B Procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. medications administered;
- dose; and
- time given.

v. level of anesthesia/sedation;
vi. oxygenation;
vii. capnography measures, if applicable;
viii. activated clotting time(s) (ACT), if applicable; and
ix. arterial blood gas, if applicable.

1.6.2.3B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness; and
v. oxygenation.

1.6.3B All physicians interpreting adult diagnostic catheterization procedures must agree on uniform diagnostic criteria and a standardized report format. The report must be free of internal inconsistencies and accurately reflect the content and results of the study, including any pertinent positive and negative findings particularly those relative to the indication for exam. The report must include but may not be limited to[46]:

1.6.3.1B Demographics:

i. date of the study;
ii. name and/or identifier of the facility;
iii. name and/or identifier of the patient;
iv. type of study;
v. indication for the study; and
vi. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

1.6.3.2B A summary of the technical aspects of the procedure including (when applicable):

i. vascular access sites:
- catheter type and size

ii. catheter placement;
iii. other.

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1.6.3.3B A summary of the results of baseline adult diagnostic catheterization testing including (when applicable);

i. description of coronary anatomy;
ii. description of angiographic projections performed for optimal visualization of the coronary artery segments[30];
iii. description of abnormality;
iv. percent stenosis of the affected coronary artery(s);
v. left ventricular function;
vi. hemodynamic measurements;
vii. acute complication(s);
viii. post-procedure recommendations;
ix. other.

1.6.3.4B The final report must be completely typewritten, including the printed name of the interpreting physician. The final report must be reviewed, signed and dated manually or electronically by the interpreting physician. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.

1.6.3.5B A summary/conclusion of the results of the procedure, including any positive and negative findings or adverse outcomes.

1.6.3.6B If appropriate, need for additional studies and/or procedures based on the results of the procedure being reported.

Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This final conclusion must resolve the clinical question or provide guidance for further studies to do so.

Comment: A record of pre-procedural and post-procedural physiologic measures and laboratory data must be maintained and immediately available when referencing the final report.

1.7B Percutaneous Coronary Intervention (PCI) reporting must be standardized in the facility. Complete information regarding all components of the procedure must be documented in the medical record, although the exact format of data reporting may vary among institutions. Generally, reporting is accomplished with a physician-authored procedure or operative note, a nursing or technical record, and an anesthesia or sedation record. In cases where procedural sedation is administered by non-anesthesia nursing staff, the sedation record may be included within the nursing record.

1.7.1B The nursing or technical record must include all technical aspects of the procedure, unless recorded in the anesthesia record, to include but may not be limited to:

1.7.1.1B Demographics:

i. name and/or identifier of the facility;
ii. name and/or identifier of the patient;
iii. date of birth and/or age of the patient;
iv. date of the study;
v. type of study;
vi. name or initials of technical, nursing and ancillary staff participating in the cardiovascular catheterization procedure; and
vii. name of the performing physician(s):
- primary operator; and

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- secondary operator (if applicable).

1.7.1.2B Baseline data:

i. height;
ii. weight;
iii. gender;
iv. anesthesia risk assessment;
v. baseline heart rate, blood pressure prior to the start of the procedure; and
vi. allergies.

1.7.1.3B Procedural data, when applicable:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;
v. physician scrub-in time;
vi. percutaneous access time;
vii. activated clotting time(s) (ACT), if applicable;
viii. arterial blood gas, if applicable;
ix. type of sedation (general anesthesia vs. moderate sedation vs. no sedation);
x. medications administered:
   - dose; and
   - time given.
xi. vascular access:
   - sites;
   - sheath size; and
   - sheath-in time.
xii. hemodynamic data;
xiii. sheath removal;
xiv. fluoroscopic exposure (list one or more of the following):
   - fluoroscopy time;
   - radiation dose (i.e., mGy);
   - dose-area product.
xv. contrast agent(s), if used, the following must be documented:
   - name of contrast(s);
   - volume(s) injected; and
   - other data, as required.
xvi. angiographic imaging to demonstrate affected coronary artery segment(s)[30]:
   - angiographic projections for optimal visualization of the affected coronary artery segment(s).
xvii. additional imaging and measures, when applicable:
   - intravascular ultrasound (IVUS);
   - intracardiac echocardiography (ICE);
   - transthoracic and/or transesophageal echocardiography;
   - method of measuring flow reserve (e.g., IFR, FFR, etc.);

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- other imaging and measures, as required.

xviii. interventional data;

- site of lesion(s);
- intervention type(s);
- intervention data;
  - angioplasty, when applicable:
    1. number of inflation(s);
    2. pounds per square inch (PSI) and duration of inflation(s);
    3. other.
  - device, when applicable;
    1. number of device(s);
    2. site of placement(s);
    3. manufacturer(s);
    4. device identification information;
       - model; and
       - serial number.
    5. size(s)/length(s);
    6. other.
- percent stenosis pre-and post-intervention;
- other.

xix. other data/information, as required.

Comment: Facilities must have the ability to measure lesion significance by one of the standard accepted flow mediated technologies and applicable staff must be able to demonstrate proficiency in the use of said technology.

(See Guidelines on Pages 64-68 for further recommendations.)

1.7.1.4B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness;
v. oxygenation; and
vi. hemostasis.

1.7.2B The anesthesia record must include all aspects of the procedure relating to anesthesia or sedation, and the patient's response to anesthesia or sedation.

1.7.2.1B Pre-procedural data:

i. height;
ii. weight;
iii. gender;
iv. anesthesia risk assessment;
v. baseline blood pressure prior to the start of the procedure; and
vi. allergies.

1.7.2.2B Procedural data:

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i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. medications administered;
- dose; and
- time given.

v. level of anesthesia/sedation;
vi. oxygenation;
vii. capnography measures, if applicable;
viii. activated clotting time(s) (ACT), if applicable;
ix. arterial blood gas, if applicable.

1.7.2.3B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness;
v. oxygenation; and
vi. post procedural infusion(s), when applicable.

1.7.3B All physicians interpreting Percutaneous Coronary Intervention (PCI) procedures must agree on uniform diagnostic criteria and a standardized report format. The report must be free of internal inconsistencies and accurately reflect the content and results of the study, including any pertinent positive and negative findings particularly those relative to the indication for exam. The report must include but may not be limited to[46]:

1.7.3.1B Demographics:

i. date of the study;
ii. name and/or identifier of the facility;
iii. name and/or identifier of the patient;
iv. type of study;
v. indication for the study; and
vi. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

1.7.3.2B A summary of the technical aspects of the procedure including (when applicable):

i. vascular access sites:
- catheter type and size

ii. catheter placement;
iii. other.

1.7.3.3B A summary of the results of PCI including (when applicable);

i. description of coronary anatomy;
ii. type of intervention;
iii. device type;

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- location;
- size;
- manufacturer;
- other.

iv. post intervention percent stenosis;

v. post intervention ventricular function;

vi. post intervention ECG changes;

vii. hemodynamic measurements;

viii. measured flow reserve results (e.g., IFR, FFR, etc.);

ix. acute outcome;

x. acute complication(s);

xi. post intervention result;

xii. post-procedure recommendations;

xiii. other.

Comment: Facilities must have the ability to measure lesion significance by one of the standard accepted flow mediated technologies and applicable staff must be able to demonstrate proficiency in the use of said technology.

1.7.3.4B The final report must be completely typewritten, including the printed name of the interpreting physician. The final report must be reviewed, signed and dated manually or electronically by the interpreting physician. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.

1.7.3.5B A summary/conclusion of the results of the procedure, including any positive and negative findings or adverse outcomes.

1.7.3.6B If appropriate, need for additional studies and/or procedures based on the results of the procedure being reported.

Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This final conclusion must resolve the clinical question or provide guidance for further studies to do so.

Comment: A record of pre-procedural and post-procedural physiologic measures and laboratory data must be maintained and immediately available when referencing the final report.

(See Guidelines on Pages 64-68 for further recommendations.)

1.8B Valve intervention reporting must be standardized in the facility. Complete information regarding all components of the procedure must be documented in the medical record, although the exact format of data reporting may vary among institutions. Generally, reporting is accomplished with a physician-authored procedure or operative note, a nursing or technical record, and an anesthesia or sedation record. In cases where procedural sedation is administered by non-anesthesia nursing staff, the sedation record may be included within the nursing record.[14,15,16,31,37,38,39,40]

1.8.1B The nursing or technical record must include all technical aspects of the procedure, unless recorded in the anesthesia record, to include but may not be limited to:

1.8.1.1B Demographics:

i. name and/or identifier of the facility;

ii. name and/or identifier of the patient;

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iii. date of birth and/or age of the patient;
iv. date of the study;
v. type of study;
vi. name or initials of technical, nursing and ancillary staff participating in the cardiovascular catheterization procedure; and
vii. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

viii. cardiovascular catheterization procedure.

1.8.1.2B Baseline data:

i. height;
ii. weight;
iii. gender;
iv. anesthesia risk assessment;
v. baseline heart rate, blood pressure prior to the start of the procedure; and
vi. allergies.

1.8.1.3B Procedural data, when applicable:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;
v. physician scrub-in time;
vi. percutaneous access time;
vii. activated clotting time(s) (ACT), if applicable;
viii. arterial blood gas, if applicable;
ix. type of sedation (general anesthesia vs. moderate sedation vs. no sedation);
x. medications administered:
- dose; and
- time given.

xi. vascular access:
- sites;
- sheath size; and
- sheath-in time.

xii. hemodynamic data;
xiii. transcatheter cerebral embolic protection (TCEP), when applicable:[38]
- site of placement; and
- manufacturer;

xiv. sheath removal;
xv. fluoroscopic exposure (list one or more of the following):
- fluoroscopy time;
- radiation dose (i.e., mGy); and
- dose-area product.

xvi. contrast agent(s), if used, the following must be documented:
- name of contrast(s);

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- volume(s) injected; and
- other data, as required.

xvii. angiography;
- type of contrast(s);
- for each angiogram:
  - time of injection;
  - site;
  - dose (ml);
  - injection rate (ml/sec);
  - pounds per square inch (PSI);
  - rise time; and
  - projection angles.
- other.

xviii. additional imaging, when applicable:
- intravascular ultrasound (IVUS);
- intracardiac echocardiography (ICE);
- transthoracic and/or transesophageal echocardiography;
- other imaging, as required.

xix. interventional data:
- affected valve(s);
- intervention type(s);
- interventional data:
  - valvuloplasty, when applicable:
    1. balloon diameter(s);
    2. number of inflation(s);
    3. for transcatheter aortic valve replacement (TAVR): pre-procedure evaluation of the distance between the aortic annulus and coronary ostia;
    4. for TAVR: when applicable, intra-procedure documentation of rapid ventricular pacing;
    5. for TAVR: when applicable; documentation of intra-procedure annual predilatation;
    6. for TAVR: post-procedure evaluation of the degree of aortic regurgitation;
    7. for transcatheter mitral valve replacement (TMVR): pre-, intra-, and post-procedural regurgitant gradients;
    8. for transcatheter tricuspid valve replacement (TTVR) in a conduit: evaluation of inner dimension of the conduit to assess for the presence of a suitable anchor point;
    9. for transcatheter pulmonary valve replacement (TPVR) in a conduit: angiograms between each sequential balloon size to rule out conduit tear;
    10. for TPVR: coronary evaluation to rule out compression with RVOT stenting;
    11. For TPVR: type, number and dilation diameter of pre-stent(s)
    12. pounds per square inch (PSI) and duration of inflation(s);
    13. other.
  - valve:

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1. site of placement(s);
2. manufacturer(s);
3. device identification information:
   - model; and
   - serial number.
4. size(s);
5. degree of pre-valve implant stenosis and regurgitation;
6. degree of post-valve implant stenosis and regurgitation;
7. other.

- when applicable, device removal;
- other.

xx. other data/information, as required.

(See Guidelines on Pages 64-68 for further recommendations.)

1.8.1.4B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness;
v. systemic oxygen saturation; and
vi. method of hemostasis

1.8.2B The anesthesia record must include all aspects of the procedure relating to anesthesia or sedation, and the patient's response to anesthesia or sedation:

1.8.2.1B Pre-procedural data:

i. height;
ii. weight;
iii. gender;
iv. anesthesia risk assessment;
v. baseline blood pressure prior to the start of the procedure;
vi. baseline oxygen saturation; and
vii. allergies.

1.8.2.2B Procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. medications administered:
   - dose; and
   - time given.
v. level of anesthesia/sedation;
vi. oxygenation;
vii. capnography measures, if applicable;
viii. activated clotting time(s) (ACT), if applicable; and
ix. arterial blood gas, if applicable.

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1.8.2.3B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness; and
v. oxygenation.

1.8.3B All physicians interpreting valve intervention procedures must agree on uniform diagnostic criteria and a standardized report format. The report must be free of internal inconsistencies and accurately reflect the content and results of the study, including any pertinent positive and negative findings particularly those relative to the indication for exam. The report must include but may not be limited to[14,15,16,31,37,38,39,40,46]:

1.8.3.1B Demographics:

i. date of the study;
ii. name and/or identifier of the facility;
iii. name and/or identifier of the patient;
iv. type of study;
v. indication for the study; and
vi. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

1.8.3.2B A summary of the technical aspects of the procedure including (when applicable):

i. vascular access sites;
ii. transcatheter cerebral embolic protection (TCEP) sites;[36]
iii. catheter placement;
iv. transseptal access technique;
v. detailed description of the procedure;
vi. other.

1.8.3.3B A summary of the results of valve intervention including;

i. description of valve anatomy to include pre-intervention annulus measurements;
ii. detailed report of hemodynamics and oximetry data;
iii. detailed description of angiography;
iv. valvular function;
- when applicable, percent stenosis pre- and post-intervention;
- when applicable, grade of regurgitation; and

v. ventricular function of the affected side;
vi. type of intervention and results;
vii. device(s) used (new):
- size;
- type; and
- manufacturer.

viii. hemodynamic measurements and interpretation;

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ix. complete diagnosis list;

x. recommendation for ongoing management;

xi. procedural complication(s);

xii. other.

1.8.3.4B The final report must be completely typewritten, including the printed name of the interpreting physician. The final report must be reviewed, signed and dated manually or electronically by the interpreting physician. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.

1.8.3.5B A summary/conclusion of the results of the procedure, including any positive and negative findings or adverse outcomes.

1.8.3.6B If appropriate, need for additional studies and/or procedures based on the results of the procedure being reported.

Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This final conclusion must resolve the clinical question or provide guidance for further studies to do so.

Comment: A record of pre-procedural and post-procedural physiologic measures and laboratory data must be maintained and immediately available when referencing the final report.

1.8.3.7B Procedures requiring the routine use of transesophageal echocardiography must be performed in an IAC-accredited facility.

(See Guidelines on Pages 64-68 for further recommendations.)

1.9B Structural heart intervention reporting must be standardized in the facility. Complete information regarding all components of the procedure must be documented in the medical record, although the exact format of data reporting may vary among institutions. Generally, reporting is accomplished with a physician-authored procedure or operative note, a nursing or technical record, and an anesthesia or sedation record. In cases where procedural sedation is administered by non-anesthesia nursing staff, the sedation record may be included within the nursing record.

Comment: Refer to Appendix B for examples qualifying structural heart interventions procedure types.

1.9.1B The nursing or technical record must include all technical aspects of the procedure, unless recorded in the anesthesia record, to include but may not be limited to:

1.9.1.1B Demographics:

i. name and/or identifier of the facility;

ii. name and/or identifier of the patient;

iii. date of birth and/or age of the patient;

iv. date of the study;

v. type of study;

vi. name or initials of technical, nursing and ancillary staff participating in the cardiovascular catheterization procedure; and

vii. name of the performing physician(s):

- primary operator; and
- secondary operator (if applicable).

1.9.1.2B Baseline data:

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i. height;
ii. weight;
iii. gender;
iv. anesthesia risk assessment;
v. baseline heart rate, blood pressure prior to the start of the procedure; and
vi. allergies.

1.9.1.3B Procedural data, when applicable:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;
v. physician scrub-in time;
vi. percutaneous access time;
vii. activated clotting time(s) (ACT), if applicable;
viii. arterial blood gas, if applicable;
ix. type of sedation (general anesthesia vs. moderate sedation vs. no sedation);
x. medications administered:
    - dose; and
    - time given.
xi. vascular access:
    - sites;
    - sheath size; and
    - sheath-in time.
xii. hemodynamic data;
xiii. sheath removal;
xiv. fluoroscopic exposure:
    - fluoroscopy time and one or more of the following:
        - radiation dose (i.e., mGy);
        - dose-area product.
xv. angiography:
    - type of contrast(s);
    - for each angiogram:
        - time of injection;
        - site;
        - dose (ml);
        - injection rate (ml/sec);
        - pounds per square inch (PSI);
        - rise time; and
        - projection angles.
    - other.
xvi. use of additional imaging, when applicable:
    - intravascular ultrasound (IVUS);
    - intracardiac echocardiography (ICE);
    - transthoracic and/or transesophageal echocardiography;

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- other imaging, as required.

xvii. interventional data:

- anatomic location of the intervention;
- intervention type(s);
- intervention data;
  - plasty, when applicable:
    1. balloon diameter, length and type;
    2. number of inflation(s);
    3. pounds per square inch (PSI) and duration of inflation(s);
    4. other.
  - device used (new and abandoned), when applicable:
    1. number of device(s);
    2. site of placement(s);
    3. manufacturer(s);
    4. device identification information:
       - model; and
       - serial number.
    5. size(s);
    6. other.
- other.

xviii. other data/information, as required.

1.9.1.4B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness;
v. oxygenation; and
vi. hemostasis.

1.9.2B The anesthesia record must include all aspects of the procedure relating to anesthesia or sedation, and the patient's response to anesthesia or sedation:

1.9.2.1B Pre-procedural data:

i. height;
ii. weight;
iii. gender;
iv. anesthesia risk assessment;
v. baseline blood pressure prior to the start of the procedure; and
vi. allergies.

1.9.2.2B Procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. medications administered;

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v. level of anesthesia/sedation;
vi. oxygenation;
vii. capnography measures, if applicable;
viii. activated clotting time(s) (ACT), if applicable; and
ix. arterial blood gas, if applicable.

1.9.2.3B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness; and
v. oxygenation.

1.9.3B All physicians interpreting structural heart intervention procedures must agree on uniform diagnostic criteria and a standardized report format. The report must be free of internal inconsistencies and accurately reflect the content and results of the study, including any pertinent positive and negative findings particularly those relative to the indication for exam. The report must include but may not be limited to[46]:

1.9.3.1B Demographics:

i. date of the study;
ii. name and/or identifier of the facility;
iii. name and/or identifier of the patient;
iv. type of study;
v. indication for the study; and
vi. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

1.9.3.2B A summary of the technical aspects of the procedure including (when applicable):

i. vascular access sites;
ii. catheter placement;
iii. transseptal access technique;
iv. detailed description of the procedure;
v. other.

1.9.3.3B A summary of structural heart intervention including (when applicable):

i. detailed description of anatomy;
ii. detailed report of hemodynamics and oximetry data;
iii. detailed description of angiography;
iv. description of ventricular systolic and diastolic function, when measured;
v. description of valvar function, when measured;
vi. type of intervention and results;
vii. device(s) used (new):
- size;
- type; and
- manufacturer.

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viii. hemodynamic measurements and interpretation;

ix. complete diagnosis list;

x. recommendation for ongoing management;

xi. procedural complication(s);

xii. other.

1.9.3.4B The final report must be completely typewritten, including the printed name of the interpreting physician. The final report must be reviewed, signed and dated manually or electronically by the interpreting physician. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.[46]

1.9.3.5B A summary/conclusion of the results of the procedure, including any positive and negative findings or adverse outcomes.

1.9.3.6B If appropriate, need for additional studies and/or procedures based on the results of the procedure being reported.

Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This final conclusion must resolve the clinical question or provide guidance for further studies to do so.

Comment: A record of pre-procedural and post-procedural physiologic measures and laboratory data must be maintained and immediately available when referencing the final report.

(See Guidelines on Pages 64-68 for further recommendations.)

1.10B Complex ACHD intervention reporting must be standardized in the facility. Complete information regarding all components of the procedure must be documented in the medical record, although the exact format of data reporting may vary among institutions. Generally, reporting is accomplished with a physician-authored procedure or operative note, a nursing or technical record, and an anesthesia or sedation record. In cases where procedural sedation is administered by non-anesthesia nursing staff, the sedation record may be included within the nursing record.

Comment: Refer to Appendix B for examples qualifying structural heart interventions procedure types.

1.10.1B The nursing or technical record must include all technical aspects of the procedure, unless recorded in the anesthesia record, to include but may not be limited to:

1.10.1.1B Demographics:

i. name and/or identifier of the facility;

ii. name and/or identifier of the patient;

iii. date of birth and/or age of the patient;

iv. date of the study;

v. type of study;

vi. name or initials of technical, nursing and ancillary staff participating in the cardiovascular catheterization procedure; and

vii. name of the performing physician(s):

- primary operator; and
- secondary operator (if applicable).

1.10.1.2B Baseline data:

i. height;

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ii. weight;
iii. BSA;
iv. gender;
v. baseline heart rate, blood pressure, and oxygen saturation prior to the start of the procedure; and
vi. allergies.

1.10.1.3B Procedural data, when applicable:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;
v. physician scrub-in time;
vi. percutaneous access time;
vii. activated clotting time(s) (ACT), if applicable;
viii. arterial blood gas, if applicable;
ix. type of sedation (general anesthesia vs. moderate sedation vs. no sedation);
x. medications administered:
- dose; and
- time given.

xi. vascular access:
- sites;
- sheath size; and
- sheath-in time.

xii. pressure waves recorded during the case;
xiii. oximetry data;
xiv. assumed or measured V02, when using Fick for cardiac output;
xv. hemoglobin, when using Fick for cardiac output;
xvi. sheath removal time;
xvii. pre- and post-procedural pedal pulse exam when using femoral arterial access;
xviii. fluoroscopic exposure:
- fluoroscopy time and one or more of the following:
  - radiation dose (i.e., mGy);
  - dose-area product.

xix. angiography:
- type of contrast(s);
- for each angiogram;
  - time of injection;
  - site;
  - dose (ml);
  - injection rate (ml/sec);
  - pounds per square inch (PSI);
  - rise time; and
  - projection angles.
- other.

xx. use of additional imaging, when applicable:

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- intravascular ultrasound (IVUS);
- intracardiac echocardiography (ICE);
- transthoracic and/or transesophageal echocardiography;
- other imaging, as required.

xxi. interventional data; and

- anatomic location of the intervention;
- intervention type(s);
- intervention data;
  - plasty(s), when applicable:
    1. balloon diameter, length and type;
    2. number of inflation(s);
    3. pounds per square inch (PSI);
    4. other.
  - device(s) used (new and abandoned), when applicable:
    1. number of device(s);
    2. site of placement(s);
    3. manufacturer(s);
    4. device identification information:
       - model; and
       - serial number.
    5. size(s);
    6. other.
- other.

xxii. other data/information, as required.

1.10.1.4B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness;
v. systemic oxygen saturation; and
vi. method of hemostasis.

1.10.2B The anesthesia record must include all aspects of the procedure relating to anesthesia or sedation, and the patient's response to anesthesia or sedation:

1.10.2.1B Pre-procedural data:

i. height;
ii. weight;
iii. gender;
iv. anesthesia risk assessment;
v. baseline blood pressure prior to the start of the procedure;
vi. baseline oxygen saturation; and
vii. allergies.

1.10.2.2B Procedural data:

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i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. medications administered:
- dose; and
- time given.

v. level of anesthesia/sedation;
vi. oxygenation;
vii. capnography measures, if applicable;
viii. activated clotting time(s) (ACT), if applicable; and
ix. arterial blood gas, if applicable.

1.10.2.3B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness; and
v. oxygenation.

1.10.3B All physicians performing complex ACHD intervention procedures must agree on uniform diagnostic criteria and a standardized report format. The report must be free of internal inconsistencies and accurately reflect the content and results of the study, including any pertinent positive and negative findings particularly those relative to the indication for exam. The report must include but may not be limited to[46]:

1.10.3.1B Demographics:

i. date of the study;
ii. name and/or identifier of the facility;
iii. name and/or identifier of the patient;
iv. type of study;
v. indication for the study; and
vi. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

1.10.3.2B A summary of the technical aspects of the procedure including (when applicable):

i. vascular access sites;
ii. catheter placement;
iii. transseptal access technique;
iv. detailed description of the procedure;
v. other.

1.10.3.3B A summary of the results of complex ACHD intervention including (when applicable):

i. detailed description of anatomy;
ii. detailed report of hemodynamics and oximetry data, when available, in a congenital heart diagram;
iii. detailed description of angiography;

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iv. description of ventricular systolic and diastolic function, when measured;

v. type of intervention and results;

vi. device(s) used (new):

- size;
- type; and
- manufacturer.

vii. hemodynamic measurements and interpretation;

viii. complete diagnosis list;

ix. recommendation for ongoing management;

x. procedural complication(s);

xi. other.

1.10.3.4B The final report must be completely typewritten, including the printed name of the interpreting physician. The final report must be reviewed, signed and dated manually or electronically by the interpreting physician. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.

1.10.3.5B A summary/conclusion of the results of the procedure, including any positive and negative findings or adverse outcomes.

1.10.3.6B If appropriate, need for additional studies and/or procedures based on the results of the procedure being reported.

Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This final conclusion must resolve the clinical question or provide guidance for further studies to do so.

Comment: A record of pre-procedural and post-procedural physiologic measures and laboratory data must be maintained and immediately available when referencing the final report.

(See Guidelines on Pages 64-68 for further recommendations.)

1.11B Pediatric cardiovascular catheterization reporting must be standardized in the facility. Complete information regarding all components of the procedure must be documented in the medical record, although the exact format of data reporting may vary among institutions. Generally, reporting is accomplished with a physician-authored procedure or operative note, a nursing or technical record, and an anesthesia or sedation record. In cases where procedural sedation is administered by non-anesthesia nursing staff, the sedation record may be included within the nursing record.

1.11.1B The nursing or technical record must include all technical aspects of the procedure, unless recorded in the anesthesia record, to include but may not be limited to:

1.11.1.1B Demographics:

i. name and/or identifier of the facility;

ii. name and/or identifier of the patient;

iii. date of birth and/or age of the patient;

iv. date of the study;

v. type of study;

vi. name or initials of technical, nursing and ancillary staff participating in the cardiovascular catheterization procedure; and

vii. name of the performing physician(s):

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- primary operator; and
- secondary operator (if applicable).

viii. cardiovascular catheterization procedure.

1.11.1.2B Baseline data:

i. height;
ii. weight;
iii. BSA;
iv. gender;
v. baseline heart rate, blood pressure and oxygen saturation prior to the start of the procedure; and
vi. allergies.

1.11.1.3B Procedural data, when applicable:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;
v. physician scrub-in time;
vi. percutaneous access time;
vii. activated clotting time(s) (ACT), if applicable;
viii. arterial blood gas, if applicable;
ix. type of sedation (general anesthesia vs. moderate sedation vs. no sedation);
x. medications administered;
xi. vascular access:
    - sites;
    - sheath size; and
    - sheath-in time.
xii. pressure waves recorded during the case;
xiii. oximetry data;
xiv. assumed or measured V02, when using Fick for cardiac output;
xv. hemoglobin, when using Fick for cardiac output;
xvi. sheath removal time;
xvii. pre- and post-procedural pedal pulse exam when using femoral arterial access;
xviii. fluoroscopic exposure[45]:
    - fluoroscopy time, and one or more of the following:
        - radiation dose (i.e., mGy);
        - dose-area product.
xix. angiography;
    - type of contrast(s);
    - for each angiogram;
        - time of injection;
        - site;
        - dose (ml);
        - injection rate (ml/sec);
        - pounds per square inch (PSI);

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        - rise time; and
        - projection angles.
    - other.

xx. use of additional imaging, when applicable:
    - intravascular ultrasound (IVUS);
    - intracardiac echocardiography (ICE);
    - transthoracic and/or transesophageal echocardiography;
    - other imaging, as required.

xxi. interventional data; and
    - anatomic location of the intervention;
    - intervention type(s);
    - intervention data;
        - plasty(s), when applicable;
            1. balloon diameter, length and type;
            2. number of inflation(s);
            3. pounds per square inch (PSI);
            4. other.
        - device(s) used (new and abandoned), when applicable;
            1. number of device(s);
            2. site of placement(s);
            3. manufacturer(s);
            4. device identification information;
                - model; and
                - serial number.
            5. size(s);
            6. other.
    - other.

xxii. other data/information, as required.

1.11.1.4B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness;
v. systemic oxygen saturation; and
vi. method of hemostasis.

1.11.2B The anesthesia record must include all aspects of the procedure relating to anesthesia or sedation, and the patient's response to anesthesia or sedation:

1.11.2.1B Pre-procedural data:

i. height;
ii. weight;
iii. body surface area (BSA);
iv. gender;
v. anesthesia risk assessment;

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vi. baseline blood pressure prior to the start of the procedure;
vii. baseline oxygen saturation; and
viii. allergies.

1.11.2.2B Procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. medications administered;
v. level of anesthesia/sedation;
vi. oxygenation;
vii. capnography measures, if applicable;
viii. activated clotting time(s) (ACT), if applicable; and
ix. arterial blood gas, if applicable.

1.11.2.3B Post-procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. level of consciousness; and
v. oxygenation.

1.11.3B All physicians performing/interpreting pediatric cardiovascular catheterization and intervention procedures must agree on uniform diagnostic criteria and a standardized report format. The report must be free of internal inconsistencies and accurately reflect the content and results of the study, including any pertinent positive and negative findings particularly those relative to the indication for exam. The report must include but may not be limited to[46]:

1.11.3.1B Demographics:

i. date of the study;
ii. name and/or identifier of the facility;
iii. name and/or identifier of the patient;
iv. type of study;
v. indication for the study; and
vi. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

1.11.3.2B A summary of the technical aspects of the procedure including (when applicable):

i. vascular access sites;
ii. catheter placement;
iii. transseptal access technique;
iv. detailed description of the procedure;
v. other.

1.11.3.3B A summary of the results of baseline pediatric cardiovascular catheterization testing including (when applicable):

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i. detailed description of anatomy;

ii. detailed report of hemodynamics and oximetry data, when available, in a congenital heart diagram;

iii. detailed description of angiography;

iv. description of ventricular systolic and diastolic function, when measured;

v. type of intervention and results;

vi. device(s) used (new):

- size;
- type; and
- manufacturer.

vii. hemodynamic measurements and interpretation;

viii. complete diagnosis list;

ix. recommendation for ongoing management;

x. procedural complication(s);

xi. other.

1.11.3.4B The final report must be completely typewritten, including the printed name of the interpreting physician. The final report must be reviewed, signed and dated manually or electronically by the interpreting physician. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.

1.11.3.5B A summary/conclusion of the results of the procedure, including any positive and negative findings or adverse outcomes.

1.11.3.6B If appropriate, need for additional studies and/or procedures based on the results of the procedure being reported.

Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This final conclusion must resolve the clinical question or provide guidance for further studies to do so.

Comment: A record of pre-procedural and post-procedural physiologic measures and laboratory data must be maintained and immediately available when referencing the final report.

(See Guidelines on Pages 64-68 for further recommendations.)

STANDARD – Procedure Volumes

1.12B The procedure volume must be sufficient to maintain proficiency in procedure performance and interpretation.[6,33,34,35]

1.12.1B The facility must have specific privileging requirements for individual operators to perform cardiovascular catheterization procedures to include, but not limited to: adult diagnostic catheterization, percutaneous coronary intervention (PCI), valve interventions, structural heart interventions, complex adult congenital heart disease (ACHD) and pediatric cardiovascular catheterization.

(See Guidelines on Pages 64-68 for further recommendations.)

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Section 1B: Procedures and Protocols
Guidelines

1.1B *All physicians and staff are required to be familiar with identifying all potential procedural complications and understand their role in managing them.*

As many management strategies for arrhythmias require chronic and/or periprocedural anticoagulation, careful evaluation, assessment and planning are needed.

1.1.2B *Because of the complexity of the cardiovascular catheterization procedures, patient safety and positive outcomes are critically dependent on the skill levels of the staff. Additional staff is needed as the complexity of the case increases and more equipment is required.*

Laboratory staffing recommendations include, but are not limited to:

- *Staff physicians must have prerequisite training and appropriate credentialing that reflects expertise in the management and treatment of acquired and congenital cardiovascular disease.*
- *It is desirable that anesthesia services be an integral part of clinical practice in the cardiovascular catheterization laboratory.*
- *Advanced practice nurses (APNs) and physician assistants (PAs) should be used in areas where they will have a maximum impact on patient care and where they can assume roles and responsibilities unique to their training and certification.*
- *At least one registered nurse should be present for every invasive procedure in the cardiovascular catheterization laboratory.*
- *Industry representatives should function according to clear policies under the direction of the laboratory manager, staff or physician.*
- *As needed, additional laboratory staff should include, but are not limited to: registered nurses (RNs), EP specialists/technologists, radiological technologists and certified nurse practitioners (NPs) and Physician Assistants (PAs).*
- *Additional appropriately-trained personnel should be provided to staff patient preparation, recover and OR areas.*
- *Other key personnel that are important for the safe and efficient function of the laboratory include: quality improvement (QI) staff, information technologists, biomedical engineers, scheduling coordinators, purchasing, inventory and supply personnel and housekeeping.*

1.2B *For patients undergoing cardiovascular catheterization procedures, additional preparation may be required on a case-by-case basis, such as typing and crossmatching of blood products in select patients and immediate availability of thoracic surgical backup.*

1.2.3B *A complete description of the procedure, including the anticipated success rates and possible complications, is best delivered in the outpatient setting before the cardiovascular catheterization procedure.*

Health care facilities should insist that clinicians administering or supervising the administration of moderate sedation meet the requirements of the American Society of Anesthesiologists.

1.4.3.1B *Complication definitions include, but are not limited to*[22-28]*:*

<u>Acute Renal Failure</u>: A sudden decline in kidney function as evidenced by either increasing creatinine and/or decreasing urine output necessitating emergent renal dialysis.

<u>Cardiac Arrest</u>: "Sudden" cardiac arrest is the sudden cessation of cardiac activity so that the victim becomes unresponsive, with no signs of circulation. If corrective measures are not taken rapidly, this condition progresses to sudden death. Cardiac arrest should be used to signify an event as described

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above that is reversed, usually by CPR, and/or defibrillation, or cardiac pacing. Sudden cardiac death should not be used to describe events that are not fatal.

Cardiac Perforation: May or may not be symptomatic and may or may not be self-sealing. It can be documented by migration of catheters/leads to the epicardial surface, resulting in pain and/or hypotension, pericardial effusion, cardiac tamponade, failure to capture, or pacing/defibrillator lead capture of the diaphragm, phrenic nerve or intercostals muscle of sufficient magnitude requiring repositioning.

Cardiac Valve Injury: Results when the manipulation of catheters and/or leads results in a tear in a valve leaflet or chordae tendinae and manifests as a new regurgitant murmur after the procedure.

Conduction Block: The condition upon which injury to the specialized cardiac conduction system occurs as a result of catheter/lead manipulation and/or ablative therapy. It can manifest as a new right/left bundle branch block or complete heart block.

Coronary Perforation: When the manipulation of catheters and/or leads in the coronary sinus results in a tear of the coronary sinus endothelium with dissection into the coronary sinus leading to perforation of the coronary sinus and the development of a pericardial effusion.

Hematoma: A collection of blood in a defined anatomic space requiring reoperation, evacuation or blood transfusion.

Hemothorax: An accumulation of blood in the thorax.

Lead Dislodgement: When movement of a lead requires reoperation after completion of the procedure.

Myocardial Infarction: Evidenced by any of the following:

- *In the absence of catheter ablation, detection of the rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) together with evidence of myocardial ischemia with at least one of the following[27]:*
    - *symptoms of ischemia;*
    - *ECG changes indicative of new ischemia (new ST-T changes or new left bundle branch block [LBBB]);*
    - *development of pathological Q waves in the ECG;*
    - *imaging evidence of new loss of viable myocardium or new regional wall motion abnormality; or*
    - *fixed (non-reversible) perfusion defects on nuclear radioisotope imaging (e.g., MIBI, thallium).*
- *In the context of a recent catheter ablation procedure, any of the following criteria[28]:*
    - *detection of ECG changes indicative of new ischemia (new ST-T changes or new LBBB), which persist for more than one hour;*
    - *development of new pathological Q waves on an ECG; or*
    - *imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.*

Pericardial Effusion: The accumulation of fluid in the pericardial space greater than a small physiological amount but not necessitating the performance of pericardiocentesis to either prevent or treat pericardial tamponade.

Pericardial Tamponade: The accumulation of fluid in the pericardial space that necessitates the performance of pericardiocentesis to either prevent or treat hemodynamic compromise.

Peripheral Embolus: The acute occlusion of an artery resulting from embolization of a cardiac or proximal arterial thrombus that does not immediately autolyse.

Pneumothorax: The presence of air in the thorax sufficient to require insertion of a chest tube.

Transient Ischemic Attack (TIA) or Stroke:

- *TIA is a brief episode of neurologic dysfunction caused by focal brain, spinal cord, or retinal ischemia without acute infarction.*

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- *Stroke is defined as infarction of central nervous system tissue.*

Venous Obstruction: as related to distally to the vascular access site, documented by swelling, pain and discoloration of an extremity and confirmed by some imagine technique demonstrating >50% diameter reduction in the affected vein.

1.4.6B *The decision for patient discharge takes into account procedural detail, patient age and health status, potential for complications (such as blood loss), and the ability of the patient (or caregivers) to evaluate signs of concern.*

1.6.1.3B xvi *Angiographic projections and optimal visualization of left and right coronary artery segments include:*

i. Left Main (LM) coronary anatomy:
  a) AP/RAO 5-10 degrees, Cranial 35-45 degrees;
  b) AP/RAO 5-15 degrees, Caudal 30 degrees;
  c) LAO 35-40 degrees, Cranial 25-35 degrees; and
  d) LAO 40-50 degrees, Caudal 25-40 degrees.
ii. Left Anterior Descending (LAD) coronary artery:
  a) AP/RAO 5-10°, Cranial 35-45°;
  b) RAO 30-45°, Caudal 30-40°;
  c) Lateral, Caudocranial 10-30°; and
  d) LAO 35-40°, Cranial 25-35°.
iii. Left Circumflex (LCX) coronary artery:
  a) AP/RAO 5-10°, Cranial 35-45°;
  b) AP/RAO 5-15°, Caudal 30°; and
  c) RAO 30-45°, Caudal 30-40°.
iv. Obtuse Marginal (OM) coronary artery:
  a) AP/RAO 5-15°, Caudal 30°.
v. Right Coronary Artery (RCA):
  a) AP/RAO 5-10°, Cranial 35-45°;
  b) LAO 35-40°, Cranial 25-35°;
  c) Lateral, Caudocranial 10-30°; and
  d) RAO 30- 45°.
vi. Posterior Descending Artery (PDA);
  a) AP/RAO 5-10°, Cranial 35-45°.
vii. Posterior Left Ventricular (PLV) coronary artery:
  a) AP/RAO 5-10°, Cranial 35-45°.
viii. Left Internal Mammary Artery (LIMA):
  a) Lateral, Caudocranial 10-30°.

1.7.1.3B, 1.8.1.3B, 1.9.1.3B, 1.10.1.3B, 1.11.1.3B *Adequate anticoagulation should be monitored with activated clotting time (ACT) throughout the procedure.*

Sedation records must include, but are not limited to the following information:

- *type of sedation (e.g., moderate sedation vs. general anesthesia);*
- *name of medication(s);*
- *dose(s) and times(s) given;*
- *route(s) of delivery;*
- *staff administering medication; and*
- *other data, as required.*

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1.8B TAVR Program[14]

Institutional volume	*1,000 catheterizations/400 PCI per year*
Interventionalist	*100 Structural procedures lifetime or 30 left-sided structural per year of which 60% should be balloon aortic valvuloplasty (Left-sided procedures include EVAR, TEVAR, BALLOON AORTIC VALVE [BAV], aortic valve [AV] and mitral valve [MV] prosthetic leak closures and ventricular septal defect [VSD] closures). Atrial septal defect/patent foramen ovale (ASD/PFO) closure are not considered left-sided procedures.*
Device training	*Suitable training on devices to be used*
Surgical program	*50 total AVR per year of which at least 10 aortic valve replacement (AVR) should be high-risk (STS score ≥6). Minimum of two institutionally-based cardiac surgeons in program (more than 50% time at hospital with surgical program).*
TAVR Surgeon	*100 AVR career, at least 10 of which are "high-risk" (STS score 6) or 25 AVR per year or 50 AVR in two years and at least 20 AVR in last year prior to TAVR initiation.* • *Experience with, and management of, peripherally inserted cardiopulmonary bypass* • *Experience with open retroperitoneal exposure of, and surgical intervention on, the iliac arteries* • *Suitable training on devices to be used*
Data registry	*All cases should be submitted to a national clinical database*
Existing programs	*>18 months: 30 TAVR (total experience)* *<18 months: 2 per month*

TMVR Program[15]

Institutional volume	*1,000 catheterizations/400 PCI per year*
Interventionalist	*50 structural procedures per year (including ASD/PFO and trans-septal punctures* *Suitable training on devices to be used*
Surgical program	*25 total mitral valve procedures per year, of which at least 10 must be mitral valve repairs.*
Data registry	*All cases should be submitted to a national clinical database.*
Existing programs	*15 mitral (total experience)* *Ongoing CME (or nursing/technologist equivalent) of 10 hours per year of relevant material*
New programs	*Because the indications are not defined, no volume criteria can be proposed yet. Assuming approval would be for high-risk cohorts, 10%-15% mortality rate at 30 days, similar to registry or published data* *65% 1-year survival rate* *Ongoing CME (or nursing/technologist equivalent) of 10 hours per year of relevant material*

TPVR Program[16]

Institutional volume	*150 congenital/structural heart disease catheterizations per year*
Interventionalist	*100 diagnostic and therapeutic cases/year including 50 congenital/structural heart intervention cases per year*
	Experience with stent implantation for branch pulmonary arteries and conduit stenosis board-certified/eligible or the equivalent in interventional cardiology, pediatric cardiology or thoracic surgery
Device training	*Suitable training on devices to be used*
Surgical program	*The program is associated with a congenital/structural open-heart program that performs >100 open surgical cases or the program is an adult-congenital cardiac program that performs 25 adult-congenital cardiac operations per year*
	There should be ECMO capabilities in the institution for the rare case when needed
Data registry	*All cases should be submitted to a national clinical database*
Outcomes	*Patients should have 80% freedom from reintervention at one year*

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TTVR Program[31]

Institutional volume	*150 congenital/structural heart disease catheterizations per year*
Interventionalist	*100 diagnostic and therapeutic cases/year including 50 congenital/structural heart intervention cases per year*
Device training	*Suitable training on devices to be used*
Surgical program	*The program is associated with a congenital/structural open-heart program that performs >100 open surgical cases or the program is an adult-congenital cardiac program that performs 25 adult-congenital cardiac operations per year*
Data registry	*All cases should be submitted to a national clinical database*

1.8.1.3B Interventional Data (TAVR)[40]

TAVR pre-procedure imaging: Initial evaluation of the aortic valve anatomy, morphology and function by transthoracic echocardiography is recommended with additional multi-modality imaging as needed.

TAVR pre-procedure evaluation: Assessment should include:

- *aortic valve morphology and function;*
- *left ventricular geometry;*
- *annular sizing; and*
- *measurements of the aortic root.*

Additional assessment should include assessment of the vascular anatomy to be used for access and the transport/deployment of the device.

TAVR periprocedural evaluation: Use of transesophageal imaging is useful to assess valve placement, valvular regurgitation and gradients and procedural complications.

1.12B Procedure Volumes

A facility should perform a minimum number of invasive cardiovascular catheterization and/or device procedures annually to maintain proficiency in procedure performance and interpretation.[6,33,34,35]

Facilities performing procedures for patients with congenital/structural heart disease should include the following[33]*:*

- *Valve Interventions: For TPVR ≥ 150 congenital/structural heart cases*
- *Structural Heart Interventions: ≥ 150 congenital/structural heart cases*
- *Complex ACHD: ≥ 150 congenital/structural heart cases*
- *Pediatric Cardiovascular Catheterization: ≥ 150 congenital/structural heart cases*

As stated, each member of the medical staff should perform a minimum number of invasive cardiovascular catheterization procedures to maintain proficiency in procedure performance and interpretation. Similarly, each member of the nursing and technical staff should assist in a minimum number of invasive cardiovascular catheterization procedures. The total volume of studies interpreted and performed by each staff member may be combined from sources other than the applicant facility. Lower volumes than those recommended here, however, should not dissuade a facility that is otherwise compliant with the IAC Cardiovascular Catheterization Standards from applying for accreditation.[6,33,34,35]

Centers specializing in pediatric and adult congenital heart disease may need to perform a relatively large percentage of complex congenital heart interventions to meet the challenges of patient size and anatomy. It is recommended that pediatric and adult congenital interventional procedures be performed at experienced centers.[33]

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Part C:
Quality Improvement

Section 1C: Quality Improvement

STANDARD – Quality Improvement (QI) Program

1.1C The facility must have a Quality Improvement (QI) Program and conduct internal quality assessment and improvement at regular intervals that are appropriate for the facility's stated purpose and include cardiovascular catheterization procedures.

1.1.1C The QI program must include the QI measures outlined below to include, but may not be limited to the evaluation and review of:

1.1.1.1C test appropriateness;

1.1.1.2C technical quality review;

1.1.1.3C safety and procedural outcomes;

1.1.1.4C interpretive quality review;

1.1.1.5C report completeness and timeliness.

STANDARD – QI Oversight

1.2C The Medical Director, Nurse Manager, Technical Manager, staff and/or an appointed QI Committee must provide oversight to the QI program including, but not limited to:

1.2.1C performance of all medical, nursing, technical and ancillary staff;

1.2.2C assessment and evaluation of patient and personnel radiation dose[17,20,21,22,23,45];

1.2.3C adherence to National Patient Safety Goals must be documented[19];

1.2.4C 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;

1.2.5C pre-defined indicators of quality and pre-defined thresholds that indicate the need for corrective action. Comparisons with external benchmarks are desirable;

1.2.6C review of procedural indications, safety and complications as well as standardized and recognized clinical outcome measures[1,2,12];

1.2.7C 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 – Test Appropriateness

2.1C As part of the ongoing QI Program, facilities must incorporate the measurement of the appropriateness of the procedure being performed based on criteria published and/or endorsed by professional medical organization(s).[1,2,3,6]

2.1.1C The facility must evaluate and document the appropriateness of the procedure performed and categorize as:

2.1.1.1C appropriate / usually appropriate;

2.1.1.2C may be appropriate; and

2.1.1.3C rarely appropriate / usually not appropriate.

2.1.2C Appropriate indications must be measured for a minimum of four cases per cardiovascular catheterization accreditation procedure type (adult diagnostic catheterization, percutaneous coronary invention [PCI], valve interventions, structural heart interventions, complex adult congenital heart disease [ACHD], pediatric cardiovascular catheterization) as possible be reviewed every six months.

(See Guidelines on Page 72 for further recommendations.)

STANDARD – Technical Quality Review

2.2C The QI Program must include an assessment of the image quality for the cardiovascular catheterization procedures being performed and have a process for documentation of complications with the goal to decrease complications.

2.2.1C The facility must evaluate the technical quality of the images obtained during the performance of cardiovascular catheterization procedures. The review must include, but not limited to, the evaluation of:

2.2.1.1C the clinical images for clarity of images and/or evaluation for suboptimal images or artifact;

2.2.1.2C completeness of the study; and

2.2.1.3C adherence to the facility imaging acquisition protocols.

2.2.2C Technical quality review must be measured for a minimum of four cases per cardiovascular catheterization accreditation procedure type (adult diagnostic catheterization, percutaneous coronary invention [PCI], valve interventions, structural heart interventions, complex adult congenital heart disease [ACHD], pediatric cardiovascular catheterization) as possible be reviewed every six months.

(See Guidelines on Pages 74 for further recommendations regarding quality assessment of diagnostic coronary angiography.)

STANDARD – Safety and Procedural Outcomes

2.3C The QI Program must include assessment of the safety of the procedures being performed and have a process for documentation of complications with the goal to decrease complications.

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2.3.1C Areas that must be assessed include, but not limited to:

2.3.1.1C all procedural complications including all serious adverse events;

2.3.1.2C patient and personnel safety must be evaluated to include, but not limited to:

i. accuracy of patient identification;
ii. medication safety;
iii. infection control measures; and
iv. staff (occupational) and patient radiation exposure monitoring according to state regulations and published guidelines where appropriate.[17,20,21,22,23,45]

2.3.1.3C documentation of adverse technical events such as equipment or device failure.

2.3.2C Participation in a national registry for all patients is strongly recommended.

2.3.3C Safety and procedural outcomes must be measured for a minimum of four cases per cardiovascular catheterization accreditation procedure type (adult diagnostic catheterization, percutaneous coronary invention [PCI], valve interventions, structural heart interventions, complex adult congenital heart disease [ACHD], pediatric cardiovascular catheterization) and be reviewed every six months.

2.3.4C Outcomes data, which must be consistent with national benchmarks when available, must be used to improve processes and procedures (refer to Appendix C).

STANDARD – Interpretive Quality Review

2.4C The facility must evaluate the quality and accuracy of the results of the cardiovascular catheterization procedure, including any pertinent positive and negative findings particularly those relative to the indication for exam.

2.4.1C Anonymized peer review, or blinded review is required when only one interpreting physician is present in the facility.

2.4.2C Interpretive quality peer review must be measured for a minimum of four cases per cardiovascular catheterization accreditation procedure type (adult diagnostic catheterization, percutaneous coronary invention [PCI], valve interventions, structural heart interventions, complex adult congenital heart disease [ACHD], pediatric cardiovascular catheterization) and be reviewed every six months.

STANDARD – Final Report Completeness and Timeliness

2.5C The facility must evaluate the final report for completeness and timeliness as required by Standards 1.5B through 1.9B.

2.5.1C Final report completeness and timeliness must be measured for a minimum of four cases per cardiovascular catheterization accreditation procedure type (adult diagnostic catheterization, percutaneous coronary invention [PCI], valve interventions, structural heart interventions, complex adult congenital heart disease [ACHD], pediatric cardiovascular catheterization) and be reviewed every six months.

Comment: Please refer to IAC Cardiovascular Catheterization Standards – Procedure Interpretation and Reports, 1.5B through 1.12B.

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Section 2C: Quality Improvement Measures
Guidelines

2.1C There should be a mechanism for education of referring physicians to improve the appropriateness of testing.

A program for documentation and reporting should be developed and include:

- *patterns of appropriate procedures performed;*
- *baseline rate of appropriate procedures;*
- *goals for improvement in the performance of appropriate procedures; and*
- *measurement of improvement rate.*

2.2C There should be a mechanism for assessing the quality of diagnostic coronary angiography.

A program for diagnostic coronary angiography assessment should include quality classification for: [47]

- *coronary contrast filling;*
- *coronary sinus reflux; and*
- *global coronary angiogram quality.*

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Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

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

3.1.1C The facility must have a minimum of two QI meetings per year, one of which is to review the results of the QI analyses and any additional QI-related topics.

(See Guidelines on Page 74 for further recommendations.)

3.1.2C All significant complications must be reviewed during these meetings.

3.1.2.1C Procedure outcomes, including success rates and complications, should be documented and recorded. Data acquired from the cardiovascular catheterization facility QI process should be used to benchmark the complication rates and outcomes of both individual practitioners and the overall cardiovascular catheterization facility.

3.1.2.2C Given the often poorly defined relationship between case volumes and outcomes, a more appropriate measure is to ensure that all major complications are reviewed by the QI committee and handled as described in the previous sections.

3.1.2.3C Complications and any identifiable root cause(s) and corrective action(s) must be reviewed and documented in efforts to improve future outcomes. Complications should be tracked and recorded to allow for trend changes to be documented and addressed.

3.1.2.4C All relevant staff must participate in at least one meeting per year. All staff are responsible for the content discussed during the QI meetings. Therefore, every attempt should be made to either attend in person, via web conference or teleconference. If unable to attend one of the two biannual meetings, the staff member is required to review the meeting minutes and document their attendance with one of the following: Medical Director, Nurse Manager, Technical Manager and/or an appointed QI Committee member.

3.2C Morbidity and Mortality (M&M) conferences must be documented.

3.2.1C The Medical Director and medical staff must attend at least one M&M conference related to cardiovascular catheterization procedures per quarter.

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Section 3C: Quality Improvement Meetings
Guidelines

3.1.1C A QI Program should be in place to assess and improve the administrative quality of the facility's operation. Administrative areas that may be assessed include, but not limited to:

- *scheduling back logs;*
- *patient wait times;*
- *accuracy of patient information during scheduling;*
- *completeness of documentation;*
- *time from completion of procedure to signature and distribution of final report;*
- *patient satisfaction and feedback;*
- *referring physician satisfaction and feedback; and*
- *patient education - on individual risk factors, smoking cessation, signs and symptoms of heart arrhythmia, cardiovascular accident, stroke or myocardial infarction and calling 911, importance of follow-up after discharge, review of discharge medications including importance of adherence to antithrombotic therapy.*

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Section 4C: Quality Improvement Documentation/ Record Retention

STANDARD – QI Documentation / Record Retention

4.1C The facility QI documentation must include, but is not be limited to:

4.1.1C the data for the QI measures;

4.1.2C minutes from the QI meetings; and

4.1.3C participant list (may include remote participation and/or review of minutes).

Comment: The QI documentation must be maintained and available to all appropriate personnel.

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Appendix A

Medical Staff Required Training and Experience

All medical staff member(s) must comply with national society training standards:

1.2.1.6A Medical staff member(s) must meet one of the published national society training standards pertaining to cardiac arrhythmias and be credentialed by the health care facility to perform cardiovascular catheterization procedures. The currently acceptable national society training standards are:

i. COCATS 4 Task Force 10: Training in Cardiac Catheterization.[3]

ii. Task Force 3: Training in Diagnostic and Interventional Cardiac Catheterization Endorsed by the Society for Cardiovascular Angiography and Interventions.[4]

iii. 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents Developed in Collaboration With the Society of Thoracic Surgeons and Society for Vascular Medicine.[5]

iv. ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). [6]

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vi. Task Force 3: Pediatric Cardiology Fellowship Training in Cardiac Catheterization Endorsed by the Society for Cardiovascular Angiography and Interventions.[8]

vii. Task Force 6: Pediatric Cardiology Fellowship Training in Adult Congenital Heart Disease.[9]

viii. Task Force 1: Training in Clinical Cardiology by the American College of Cardiology.[10]

ix. American Board of Internal Medicine. Policies and Procedures for Certification.[11]

x. SCAI Expert Consensus Statement for Advanced Training Programs in Pediatric and Congenital Interventional Cardiac Catheterization.[25]

xi. Other national society training standards may be considered appropriate subject to review and approval by the IAC Cardiovascular Catheterization Board of Directors.

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Appendix B

Fluoroscopy: Equipment and Instrumentation

When fluoroscopy is required, equipment and instrumentation must include, but not limited to:

1.4.7B A fixed or portable, single or biplane angiography and/or fluoroscopy system that must meet the following specifications:

i. high quality, subtracted digital imaging;
ii. road-mapping (recommended) with ability to refer back to an unsubtracted live image;
iii. last image hold is desirable;
iv. pulsed fluoroscopy is desirable;
v. dose measurement capability and/or fluoro time;
vi. Digital Imaging and Communications in Medicine (DICOM) compatible digital image storage with capability of storing uncompressed images on portable format without loss of image resolution (as applicable);
vii. ability to display and review prior relevant images during the procedure is desirable;
viii. minimum detector diameter of 9 inches;
ix. minimum spatial resolution of matrix of 1000 x 1000;
x. minimum contrast resolution to see the 1.5 mm hole in a standard phantom (see Page 4, Section 4B (low contrast performance) of Guidance Document Fluoro QA Guide posted on intersocietal.org/ep/seeking/sample_documents.htm.
xi. image monitor performance using the Society of Motion Picture and Television Engineers (SMPTE) pattern; and
xii. for equipment installed before 2006 that does not display cumulative dose and or dose area product (DAP), documentation of fluoroscopy time and the number of images per procedure is acceptable.

Structural Heart Interventions: Qualifying Procedure Types

When performing structural heart interventions in the adult patient:

1.9B Any procedure where a patent foramen ovale (PFO) or patent ductus arteriosus (PDA) persists into adulthood or surgical repair of acquired heart disease requires an intervention, but not limited to:[43]

i. transcatheter closure device for a PFO;
ii. transcatheter closure device for a PDA;
iii. transcatheter closure device for a secundum atrial septal defect (only in the absence of other congenital heart defects);
iv. ventricular septal defect (small and only in the absence of other congenital heart defects);
v. transcatheter occlusion of the left atrial appendage (only in the absence of a congenital heart defect(s));
vi. occlusion of a paravalvular leak;
vii. post-myocardial infarction ventricular septal rupture;
viii. interventions (e.g., coil/closure device, etc.) in a repair of one of the procedure types listed above;
ix. other.

Complex ACHD: Qualifying Procedure Types

When performing complex congenital heart defect (CHD) interventions in the adult patient:

1.10B Any intervention, other than transcatheter valve replacement, where the following CHD is present (pre- or post-operative), but not limited to:[42,43,44]

i. atrioventricular septal defect (AVSD), also known as atrioventricular canal (AVC), also known as complete atrioventricular canal (CAVC);
ii. tetralogy of Fallot (ToF);

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iii. transposition of the great arteries (d-TGA or l-TGA);

iv. coarctation of the aorta (CoA);

v. Shones disease (mitral stenosis, sub aortic/aortic stenosis, coarctation of the aorta);

vi. total or partial anomalous pulmonary venous return (TAPVR, PAPVR), also known as TAPVC or PAPVC;

vii. Ebstein's anomaly (ventricularization of the tricuspid valve);

viii. single ventricle (Left or Right);

ix. truncus arteriosus;

x. ventricular septal defect (VSD);

xi. pulmonary stenosis (interventions other than TPVR);

xii. bicuspid aortic valve (BAV) (interventions other than TAVR);

xiii. any procedure where a surgical repair of a CHD requires an intervention, but not limited to:

   a. dilatation of a conduit;

   b. fenestration of a baffle or a closure of a fenestration of a baffle;

   c. coil / closure device in the presence of a repair of one of the CHD listed above (not PFO or PDA closure.

xiv. other.

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Appendix C

Quality Improvement Measures

Requirements for safety and procedural outcomes:

2.2C A policy for adherence to National Patient Safety Goals must be documented, and include at a minimum:

i. Accuracy of patient identification:
   a. Use at least two patient identifiers when providing care, treatment or services.

ii. Medication safety:
   a. Label all medication containers on and off the sterile field including syringes, medicine cups, IV bags and basins.
   b. For all containers on a sterile field, or for immediate use, the name and concentration of the medication in the container is required. For all medication containers, not on a sterile field, the medication name, concentration and expiration date must be clearly identified.
   c. Describe the dispensing, dilution and expiration period for intravenous solutions used by the facility.

iii. Infection control measures consistent with CDC and OSHA guidelines to include, but not limited to:
   a. hand hygiene;
   b. use of universal precautions, use of appropriate personal protection devices and practices;
   c. practices to prevent surgical site infections;
   d. development or identification of process measures and outcomes for evaluation of health care related infections;
   e. discouragement of the use of multiuse vials for dispensing medications;
   f. disinfection and sterilization practices on all surfaces contacted by the patient or any blood and body fluids after a procedure and on all instruments consistent with CDC policy; and
   g. use of sterile covers on ultrasound transducers and operator managed controls during sterile procedures are required.

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