IAC
INTERSOCIETAL ACCREDITATION COMMISSION
CARDIOVASCULAR CATHETERIZATION

# IAC Standards and Guidelines for Cardiovascular Catheterization Accreditation

## Accreditation Standards

AUGUST 2025

### 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.

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

These accreditation Standards 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.*

**Standards that are highlighted are changes that were made as part of the August 15, 2025 revision and effective immediately. The majority of these changes are minor and were revised for clarification and consistency with existing IAC interventional *Standards* only.**

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.

# 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.

Comment: After initial certification, maintaining the certification is strongly recommended.

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 (ABP) in pediatric cardiology, by the Royal College of Physicians and Surgeons of Canada in pediatric cardiology, or by the American Board of Internal Medicine (ABIM) 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 Physicians of national and/or international renown must be able to demonstrate the following:

i. H-1B visa for foreign medical graduates;
ii. distinguished foreign teaching physician medical license or full medical license issued by the State Board of Medical Examiners;
iii. full and unrestricted license(s) to practice medicine issued by the appropriate licensing agencies in the applicant's home country or elsewhere;



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iv. proof of graduation from a medical school in a foreign country to include proof of completion of specialized training for the procedure(s) performed; and

v. proof of certification and/or membership in an appropriate medical specialty, academy, college and/or evaluation organization.

1.1.1.6A 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 reviewing and updating 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 dated on the reviewed document or manual.

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

1.1.2.5A Demonstrating 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. (See Appendix A for further guidance)

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:



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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.

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

1.1.3.3A The Medical Director must fulfill hospital and state CME requirements.

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

## 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 one or more the following:

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.

Comment: After initial certification, maintaining the certification is strongly recommended.

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 (ABP) 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. 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



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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. 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] and

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

- 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 Physicians of national and/or international renown must be able to demonstrate the following:

i. H-1B visa or current U.S. Government Department of Homeland Security regulations for foreign medical graduates;

ii. distinguished foreign teaching physician medical license or full medical license issued by the State Board of Medical Examiners;

iii. full and unrestricted license(s) to practice medicine issued by the appropriate licensing agencies in the applicant's home country or elsewhere;

iv. proof of graduation from a medical school in a foreign country to include proof of completion of specialized training for the procedure(s) performed; and

v. proof of certification and/or membership in an appropriate medical specialty, academy, college and/or evaluation organization.

1.2.1.8A 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.

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 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.



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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.). (See Appendix A for further guidance)

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.

1.2.3.3A Medical staff must fulfill hospital and state requirements.

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

## STANDARD – Nurse Manager

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

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)
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).



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

i. at least six months of experience in critical care, 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, nursing staff and/or any ancillary staff who report to the Nurse Manager;

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;

1.3.2.9A knowledge and maintenance of sterile technique;

1.3.2.10A a nurse administering moderate sedation during the procedure should not have other responsibilities that could compromise patient assessment; and

1.3.2.11A in cases where more than moderate sedation is used, an anesthesia provider should be present, and policies should be drafted for the administration of medications that are consistent with hospital credentialing and state guidelines.

*(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, acquired and/or congenital heart disease, coronary artery disease, cardiovascular assessment 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.).

1.3.3.2A All CE hours must be approved (i.e., American Nurses Credentialing Center [ANCC-Category I], AMA Category I) and/or the nursing staff member must 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 Nurse Managers 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.

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

1.3.3.4A The Nurse Manager must fulfill hospital and state CE requirements.

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

## STANDARD – Technical Manager

1.4A The manager of the technical and nursing staff must be an appropriately credentialed technologist and/or 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 [RT(R)] 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



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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.

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;

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; and

1.4.2.9A knowledge and maintenance of sterile technique.

*(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, acquired and/or congenital heart disease, 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,



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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.

1.4.3.4A The Technical Manager must fulfill hospital and state CE requirements.

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

## 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
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;

i. A nurse administering moderate sedation during the procedure should not have other responsibilities that could compromise patient assessment.



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ii. In cases where more than moderate sedation is used, an anesthesia provider should be present, and policies should be drafted for the administration of medications that are consistent with hospital credentialing and state guidelines.

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;

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; and

1.5.2.10A knowledge and maintenance of sterile technique.

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

1.5.3A Continuing Education (CE) Requirements

1.5.3.1A The 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, acquired and/or congenital heart disease, coronary artery disease, cardiovascular assessment 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.).

1.5.3.2A 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.

1.5.3.4A The nursing staff must fulfill hospital and state CE requirements.

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



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## 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 [RT(R)] 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 (RT[R]) 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.

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 Technologist(s) Responsibilities

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

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



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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);

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

1.6.2.17A knowledge and maintenance of sterile technique.

*(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, acquired and/or congenital heart disease, 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.).



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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 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.

1.6.3.4A The technologist staff must fulfill hospital and state CE requirements.

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

## 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)
iv. Nurse Practitioner (NP)

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



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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 Advanced Practice Provider Responsibilities:

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. knowledge of 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;
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 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



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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, acquired and/or congenital heart disease, coronary artery disease, cardiovascular assessment and/or patient management every three years.

Comments: 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.).

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.

1.7.4.4A The advanced practice provider must fulfill hospital and state CE requirements.

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

## 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.

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



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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 retained by the facility, assume the responsibilities as outlined in Standard 1.10.2A and meet the following qualifications:

1.10.1A Medical Physicist Required Training and Experience

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 Physicists (CCPM) in diagnostic medical physics or equivalent.

1.10.1.2A Passed Part 2 of the ABR examination and completed a CAMPEP-approved residency in medical physics discipline, including diagnostic imaging, is acceptable. As outlined above, a recognized board certification is required before the next accreditation cycle.

1.10.1.3A If necessary for each state, the medical physicist must be licensed or certified as a diagnostic medical physicist.

1.10.2A Medical Physicist Responsibilities

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

1.10.2.1A The medical physicist should regularly perform radiation measurements, dosimetric calculations, and equipment performance evaluations of fluoroscopic equipment to maintain competence in performing these activities.

1.10.2.2A The physicist should observe at least one fluoroscopically guided procedure within each accreditation modality/area annually.



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1.10.2.3A Acceptance (initial) tests and annual surveys (or more frequently as governed by state and local regulations) for equipment performance evaluation, including:

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

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

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

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

1.10.2.4A Where necessary (see 3.1.1A), evaluation of the radiation shielding adequacy and integrity ensuring necessary radiation protection to individuals in all adjacent areas (only necessary at the initial survey, after any modifications to the structural shielding or replacement of the imaging equipment).

1.10.2.5A Assessment of proper functioning of collimators and tissue compensation filters.

1.10.2.6A Provide a written summary report to the Medical Director or Radiation Safety Officer and include any identified issues requiring corrective action or recommendations for improvement.

1.10.2.7A Provide written guidance for any patient and/or staff dosimetry issues.

1.10.2.8A Provide radiation training for personnel as required.

i. Radiation instruction should include considerations for pregnant patients and staff.

Comment: Facilities must follow best practices to lower radiation exposure to patients, operator and cardiovascular catheterization staff (See Appendix A for further guidance)

1.10.2.9A Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist in the data collection under the direct supervision of the medical physicist (i.e., the physicist must be on premises and immediately available). The medical physicist must review and approve all such data. The medical physicist remains personally responsible for tasks.

1.10.3A Continuing Education (CE) Requirements

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

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

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

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

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



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|---|---|
| *1.1A, 1.2A, 1.3A, 1.4A, 1.5A, 1.6A, 1.7A and 1.10A* | *All staff are highly encouraged to seek membership in professional membership societies as related to their scope of practice.* |
| *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 Update6 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 – General Facility Standards

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

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

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

## STANDARD – Areas (Physical Facility)

2.2A Area requirements include, but are not limited to:[7,50,51,52,53,54,55,56]

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

2.2.1A General Areas

2.2.1.1A waiting, reception and patient/staff bathrooms;

2.2.1.2A patient education, consultation and examination areas; and

2.2.1.3A readily accessible handwashing/sanitation for staff.

2.2.2A Procedure Areas

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

2.2.2.2A substerile scrub area;

2.2.2.3A substerile entrance(s) must have:

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

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

i. leaded wall with a large leaded viewing window if the procedure room is contiguous with the control room;

ii. two-way intercom system;

- desk space adequate to accommodate fluoroscopy monitors, hemodynamic/physiologic recording systems, etc.

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

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



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

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

v. General Room Lighting: Overhead and task lighting must be adequate to perform procedures, clinical evaluation and patient treatment. The overhead lighting must be able to be dimmed during fluoroscopy. It is recommended that the overhead lighting be controlled by a foot pedal used by the operating physician.
- Additionally, the procedure room must have surgical lighting for any procedure requiring access, device implantation, or that may require surgical intervention.

vi. Room Power: The facility must have a plan that outlines the response to unexpected power loss or computer function, such as moving the patient to another procedure room in the immediate vicinity.
- When normal power is not available, emergency power should provide a minimum of 10 minutes of fluoroscopy, and at least one hour of backup power for the computers, monitoring equipment and ancillary equipment.
- There should be sufficient emergency power supply to run fluoroscopy for one hour and run the remainder of the x-ray system components, including lighting, for at least 24 hours.
- The utilization of emergency power must be visible to the operator in the normal working position.
- An uninterruptible power supply for all computer equipment is required.
- X-ray equipment and computers should not require rebooting during the transition between normal and emergency power or during power line instabilities.

2.2.2.6A Interpretation / Dictation Areas

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

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

2.2.2.7A Storage Areas

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

ii. Adequate space must be provided for
- patient records, reports and digital data storage areas;
- administration records and support areas; and
- equipment/supply storage areas.

*(See Guidelines on Page 33 for further recommendations.)*

2.2.2.8A emergency cardiovascular surgical support must be immediately available in case of life-threatening procedural complications;



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Comment: Refer to Appendix A 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.[7,50,51,52,53,54,55,56]

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]

2.2.3A The following procedure room type/area must comply with all Standards listed above (2.2.1A through 2.2.2A) and have or meet, but not limited to, the following:[6]

2.2.3.1A 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. cardiovascular catheterization specific equipment:
   - contrast injectors.

ii. defibrillator;

iii. electrocardiogram and hemodynamic monitoring equipment capabilities as described in Standard 2.3.2A;

iv. 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).

v. non-invasive blood pressure monitor;

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

vii. emergency equipment and supplies as required by Standard 4.4A;

viii. 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;
   - Impella; and
   - other.

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



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

xi. 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.

2.2.3.2A 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. cardiovascular catheterization-specific equipment:
   - contrast injectors.

ii. defibrillator;

iii. electrocardiogram and hemodynamic monitoring equipment capabilities as described in Standard 2.3.2A;

iv. 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).

v. non-invasive blood pressure monitor;

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

vii. emergency equipment and supplies as required by Standard 4.4A;

viii. snares and other retrieval devices;

ix. 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; and
   - other.

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

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

xii. 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 32 for further recommendations.)*

2.2.3.3A Pediatric Cardiovascular Catheterization Suites: Procedure rooms performing pediatric cardiovascular catheterization procedures have similar requirements as that of rooms detailed in Standard 2.2.3.1A 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;



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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 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 32 for further recommendations.)*

## STANDARD – Equipment and Instrumentation

2.3A Equipment Type

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

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

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

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

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



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

2.4A Equipment, Instrumentation and Supplies Quality Control

2.4.1A Equipment and instrumentation must be appropriate, in good working condition, and routinely inspected for safety and proper functionality per local, state, and/or federal regulations.

2.4.2A Preventive maintenance (PM) is required according to the manufacturer's recommendations.

2.4.3A There must be a process to check inventory of disposable supplies (e.g., catheters, wires, balloons, stents, embolic protection devices, contrast) and medications to ensure they are not expired and are readily available during a procedure.

2.5A Quality Control Documentation

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



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*2.2A The participation of an ergonomics expert in the planning should be considered as a measure to comply with Occupational Safety and Health Administration standards.*

*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.*

*Preparedness for High Risk, Low Frequency Events: Protocols and Simulation Drills*[62,58]

- *Protocols should include how to activate the key participants and the location and inventory of diagnostic and therapeutic tools.*
- *Simulation drills with all team members together should be performed at routine intervals in the cardiovascular catheterization laboratory to practice response to these high risk, low frequency events, and may be coordinated by the medical and administrative/nursing directors as well as a nurse educator.*
- *These simulation drills should include rapid assessment of a complication, activation of emergency protocols as well as mobilization of therapeutic interventions.*
- *In the case of an actual complication in the CCL, tools such as same-day or next-day debriefing, root-cause analysis, and M&M case reviews should be implemented to optimize protocol to improve CCL readiness and patient outcomes.*
- *Examples include natural disasters and infectious outbreaks, such as the response to the COVID-19 pandemic.*
- *Emergency preparedness protocols may also be required.*
- *For facilities without onsite cardiac surgical backup, mock transfer drills with EMS and "receiving" hospital should be performed.*

*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.*

*2.2.3.2A 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]

*2.2.2.6A and 2.2.2.7A An additional 45 inches of desk space is suggested for a two-monitor reading station or single-monitor workstation.*

*2.2.2.7A 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.*

*2.2.2.5A Integrated data display systems provide flexibility and efficiency in data display; it is advisable to have separate backup monitors in case of failure.*

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

*2.2.3A Intracardiac Echocardiography (ICE) may be useful as an adjunctive imaging modality during complex procedures.*

*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: Fluoroscopy

## STANDARD – Examination Areas

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

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

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

## STANDARD – Equipment and Instrumentation

3.4A Fluoroscope

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

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

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

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

## STANDARD – Equipment and Instrumentation Quality Control

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

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

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



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

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

## STANDARD – Quality Control Documentation

3.6A All quality control results must be documented and reviewed.

3.6.1A Documentation of the physicists' evaluation, preventative maintenance, 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.

3.6.1.1A All items requiring corrective action shall be addressed in a timely manner with appropriate documentation indicating that the performed corrective action has adequately addressed the identified issue.

## STANDARD – Radiation Safety

3.7A Personnel

3.7.1A Fluoroscopic equipment may only be operated by individuals with the requisite training and credentials who meet all local, state and federal requirements and operate the equipment within their scope of practice.

3.7.2A Personnel Required Training and Experience:

3.7.2.1A All individuals in the fluoroscopic procedure room during the procedure must have documented radiation safety training that is approved by a medical physicist and that meets state requirements. Radiation safety training should align with the National Council on Radiation Protection and Measurements *Commentary 33 – Recommendations for Stratification of Equipment Uses and Radiation Safety Training for Fluoroscopy (2023)*.

3.7.2.2A In addition to radiation safety training, all individuals operating the fluoroscopy equipment must have machine specific training for each make and model of the fluoroscope operated.

3.7.3A Personnel Responsibilities:

3.7.3.1A Personnel responsibilities may include, but are not limited to:

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

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



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

3.7.4A Continuing Education (CE) Requirements:

3.7.4.1A At least one hour of CE in radiation protection related to fluoroscopy must be obtained and documented every three years for individuals operating the fluoroscope.

3.8A Radiation Safety Program

3.8.1A General Radiation Safety

3.8.1.1A There must be a comprehensive written radiation safety program that meets state and federal safety mandates and includes all relevant policies and procedures.

3.8.1.2A The radiation safety officer shall have oversite of and review all the following:

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

ii. personal radiation protective garment and accessory evaluation;

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

iv. patient radiation exposure summary reports; and

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

3.8.2A Occupational and Patient Radiation Dose

3.8.2.1A The radiation safety program must include policies and procedures for monitoring and reviewing occupational and patient radiation doses.

3.8.2.2A Occupational Radiation Exposure and Monitoring

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

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

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

3.8.2.3A Pregnant Staff

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

3.8.2.4A Patient Doses

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



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

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

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

3.8.2.5A Protocol Modification

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

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

3.8.2.6A Pregnant Patient

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

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

3.8.3A Protective Equipment

3.8.3.1A The facility must have sufficient radioprotective apparel and ancillary shields for staff. The apparel and shields must be evaluated annually with documentation per institutional guidelines and policies and in compliance with state and federal guidelines.



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# Section 4A: Safety

## STANDARD – Patient and Staff Safety

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

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

4.1.2A There must be written policies and procedures for:

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

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

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

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

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

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

4.2A Medication Safety

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

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

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

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

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

4.3A Contrast Safety

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



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

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

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

4.3.5A Contrast material must be clearly labeled.

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

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

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

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

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

4.4A Emergency Equipment

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

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

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

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

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

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

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

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

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



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

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

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

4.5A Anesthesia

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

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

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

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

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

4.5.5.1A non-invasive blood pressure;

4.5.5.2A pulse oximetry;

4.5.5.3A ECG monitoring; and

4.5.5.4A capnography (CO2) monitoring, if applicable.

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

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

4.6A Sterilization of Medical Instruments:

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

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

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

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

4.6.4.1A comprehensive training requirements for all staff assigned;



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

4.6.4.3A sterilizer maintenance as needed with records of service;

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

4.6.4.5A instructions for process monitoring and reporting;

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

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

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

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



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# Section 5A: Administrative

## STANDARD – Patient Confidentiality

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

## STANDARD – Patient or Other Customer Complaints

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

## STANDARD – Primary Source Verification

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

## STANDARD – Record Retention

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

## STANDARD – Information Security

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

# Section 5A: Administrative Guidelines

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



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# Part B: Process

## Section 1B: Procedures and Protocols

### STANDARD – Procedure Overview

1.1B The 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 69-75 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 In cases where deep sedation is used, an anesthesia provider, or provider certified in deep sedation, should be present, and policies should be drafted for the administration of medications that are consistent with hospital credentialing and state guidelines.

1.1.3B Appropriate staff must be available to assist the patient should an adverse event occur during the procedure and/or during recovery.

1.1.3.1B For primary PCI, three non-physician medical staff are required.

*(See Guidelines on Pages 69-75 for further recommendations.)*

1.1.4B All staff must observe adherence to:

1.1.4.1B standardized uniformly applied universal precautions in every aspect of patient care;

1.1.4.2B national patient safety goals (e.g., medication safety);

1.1.4.3B infection control measures consistent with CDC and OSHA guidelines; and

1.1.4.4B sterile technique.

1.1.5B 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. 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.

Comment: Facilities must comply with state and federal radiation guidance documents to ensure radiation protective garments have appropriate lead equivalencies.

### STANDARD – Procedure Requirements

1.2B Prior to performance of the procedure:



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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 and sedation initiation 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. Patient identification must be confirmed with unanimous agreement on the procedure to be performed.

If PCI is considered, an additional time out must be conducted to include, but not limited to:

- appropriate use classification;
- radiation exposure and contrast dose;
- appropriateness or need for intravascular imaging or physiologic assessment;
- issues regarding dual antiplatelet therapy;
- adequate pre-treatment with aspirin and P2Y12- receptor inhibitors; and
- baseline hemodynamics.

For structural heart and valve intervention procedures, an additional time out must be conducted to include, but not limited to:

- device/valve type;
- valve size;
- direction of valve; and
- surgical bailout strategy.

Comment: If team members rotate out, then it is their responsibility to brief their replacement, who should introduce themselves to the team and announce their role.

All procedures must be explained to the patient and/or the parents or guardians of those unable to give informed consent. A risk calculator should be used to estimate pre-procedure risk prior to informed consent. Consent must be obtained in a manner consistent with the rules and regulations required by the hospital or facility. Each institution should have a written policy that describes the process used to obtain informed consent, including timing, documentation, and surrogate decision-maker issues, as well as circumstances that would allow for exceptions to obtaining informed consent, such as emergency ST-Elevation Myocardial Infarction (STEMI) in a patient unable to provide consent. If the patient has a Do Not Resuscitate (DNR) code status, it is important to discuss temporary suspension of the order with the patient or health care proxy and document the terms and duration of the temporary suspension. 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 69-75 for further recommendations.)*

1.2.4B A fire safety evaluation must be performed prior to the start of the procedure whenever there is



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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 (H&P) must be performed within 30 days of the procedure, should be in the chart prior to the procedure, and should include documentation of relevant laboratory testing, medications, allergies and bleeding disorders.

1.2.5.1B Prior to emergency procedures, a targeted history and limited physician examination are sufficient, but a complete H&P must be added following the procedure.

1.2.5.2B For outpatient procedures with the complete H&P performed between 30 days and 24 hours prior to the procedure, an interim H&P must be documented by the attending physician or advanced practice provider, detailing an updated history, vitals, and examination, as well as any interim changes, within 24 hours of the procedure.

1.2.5.3B For inpatient procedures, a complete H&P should be performed within 24 hours of admission.

1.2.5.4B The patient's advance directive, living will, and DNR status must be confirmed prior to the procedure.

1.2.5.5B Allergies to intravenous contrast must be documented to include the specific reaction.

1.2.5.6B A policy or protocol must be in place for the management of patients at risk for or presenting with chronic kidney disease (CKD).

*(See Guidelines on Pages 69-75 for further recommendations.)*

1.2.5.7B A policy or protocol must be in place detailing the process for documentation and review of contrast use.

i. pre-procedure intravenous (IV) hydration with normal saline should be provided in patients at increased risk for chronic kidney disease CKD if not contraindicated;
ii. the total contrast dose should be monitored, and risk scores can be used to identify a suggested limit; and
iii. for those with compromised renal function, a strategy of recording the left ventricular end diastolic pressure and using it to guide fluid administration during the procedure should be considered.

1.2.5.8B Total contrast volume administered to the patient must be monitored in real time and limited to as low as clinically possible.

i. staff should inform physicians when these limits have been reached.

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;



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- 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.

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: 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 If performing a high-risk procedure staff should consider 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



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

*(See Guidelines on Pages 69-75 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 measured after administration of the initial dose and subsequently based with activated clotting time (ACT) throughout the procedure.

1.3.5.1B Documentation of therapeutic ACT must be obtained prior to PCI.

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

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).

1.3.8B All medications must be recorded in a procedure log or electronic record and signed by the attending physician.

1.3.8.1B Records must be easily accessible, particularly when the patient leaves the procedure room.

1.3.9B Appropriate documentation of the physician's verbal orders needs to be carried out by the recording technologist or nurse and these orders confirmed by the performing physician at the close of the case with a signature.

Comments: All elements of the procedure should be recorded into an electronic record that documents the procedure and events that took place. This procedure report should be generated immediately post-procedure and included in the patient's chart prior to transferring to the next level of care.



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If a procedure report cannot be placed in the medical record immediately after the procedure, then a brief progress note should be entered with sufficient information for immediate post-procedure care.

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;
xix. pneumothorax;
xx. stent thrombosis;
- other adverse events:
  - stent loss;
  - retained foreign body;



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- 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.

Comments: The facility should have a protocol or order set for contrast allergies/reaction.

The facility should have protocols regarding complication response plans.

*(See Guidelines on Pages 69-75 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 69-75 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 policy in place for communicating any significant changes between the



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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;
v. allergies; and
vi. indication for the procedure.

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 and level of sedation (general anesthesia vs. deep sedation vs. moderate sedation vs. no sedation);
x. medications administered;



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- 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 more of the following;
  - 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 69-75 for further recommendations.)*

xvii. additional imaging and measures, when applicable:
- intravascular ultrasound (IVUS);
- optical coherence tomography (OCT);
- 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:



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

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



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ii. catheter placement;
iii. other.

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.

Comments: 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.

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;



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

viii. indication for the procedure.

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 and level of sedation (general anesthesia vs. deep sedation 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. 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



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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.);
- 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. inflation pressures (atm) 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 69-75 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;



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

1.7.2.2B 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;
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;



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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;
- 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.

Comments: 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.

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 69-75 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]



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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;
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 and level of sedation (general anesthesia vs. deep sedation 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:[36,38]
- site of placement; and
- manufacturer;



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xiv. sheath removal;

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

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



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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. inflation pressures (atm) and duration of inflation(s);
13. other.

- valve:
  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 69-75 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;
vii. allergies; and
viii. indication for the procedure.

1.8.2.2B Procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;



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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.

1.8.2.3B 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;[36,38]
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;



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- 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;

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.

Comments: 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.

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 69-75 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;



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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;
vii. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

viii. indication for the procedure.

1.9.1.2B 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.

1.9.1.3B 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 and level of sedation (general anesthesia vs. deep sedation 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;



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- site;
- dose (ml);
- injection rate (ml/sec);
- inflation pressures (atm);
- rise time; and
- projection angles.

- other.

xvi. use of additional imaging, when applicable:

- intravascular ultrasound (IVUS);
- intracardiac echocardiography (ICE);
- transthoracic and/or transesophageal echocardiography;
- 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. inflation pressures (atm) 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;



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

1.9.2.2B 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.

1.9.2.3B 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.



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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.

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.

Comments: 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.

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 69-75 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 of 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:



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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;
vii. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

viii. indication for the procedure.

1.10.1.2B 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.

1.10.1.3B 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 and level of sedation (general anesthesia vs. deep sedation 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;



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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);
  - inflation pressures (atm);
  - 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. inflation pressures (atm);
    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;



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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;
vii. allergies; and
viii. indication for the procedure.

1.10.2.2B 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.

1.10.2.3B 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;



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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;
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.

Comments: 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.

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 69-75 for further recommendations.)*



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1.11B 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;
vii. name of the performing physician(s):
- primary operator; and
- secondary operator (if applicable).

viii. cardiovascular catheterization procedure; and
ix. indication for the 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 and level of sedation (general anesthesia vs. moderate sedation vs. deep sedation vs. no sedation);
x. medications administered;
xi. vascular access:
- sites;



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- 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);
  - inflation pressures (atm);
  - 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. inflation pressures (atm);
    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.



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

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



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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):

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.



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Comments: 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.

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 69-75 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 69-75 for further recommendations.)*

## 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.*



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*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.*

*1.2.5.6B A policy or protocol for the management of patients at risk for or presenting with chronic kidney disease (CKD should include, but is not limited to:[62]*

- *Patients with baseline renal insufficiency (eGFR <60 mL/min/1.73 m2) and/or elevated risk scores are at increased risk of developing contrast-induced nephropathy (CIN). The only strategies consistently shown to reduce the risk of CIN are hydration and minimizing the contrast dose.*
- *Pre-procedure intravenous (IV) hydration with normal saline should be provided in patients at increased risk for CKD if not contraindicated.*
- *The total contrast dose should be monitored, and risk scores can be helpful in identifying a suggested limit.*
- *One tool uses the ratio of contrast volume to creatinine clearance (CrCl), with a ratio of contrast volume/CrCl >3.7 as predictive of renal injury.*
- *In addition, particularly for those with compromised renal function, a strategy of recording the left ventricular end diastolic pressure and using it to guide fluid administration during the procedure should be considered.*

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

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

*Cardiac Arrest: "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 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 99$^{th}$ 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;*



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- *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.*
- *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.*

*Examples of High Risk, Low Frequency Complications for Protocol Implementation[61]*

*Elements to Include:*

- *Location of diagnostic tools for rapid assessment*
- *Activation numbers of key participants*
- *Location and inventory of therapeutic tools*

*Vascular Complications:*

- *Anticoagulation and antiplatelet reversal protocols*
- *Paging protocol for immediate assistance from surgery or an endovascular specialist*
- *Protocol for manual compression, blood availability, and immediate invasive angiography to allow balloon tamponade or stenting of bleeding vessel where available (e.g., covered stent).*
- *Protocol for obtaining emergency imaging such as non-contrast computed tomography for suspected retroperitoneal bleed or computed tomography angiography to identify bleeding site, as examples.*
- *Protocol for severe forearm hematoma management.*

*Acute Stroke:*

- *Protocol for calling stroke alert and activating stroke team (including a neurologist, neurological interventionalist, and access to emergent neuroimaging), including rapid brain imaging protocol.*
- *Protocol for emergent transfer to institutions for higher level care when appropriate*

*Emergency Pacing:*

- *Protocol for emergency transcutaneous and transvenous pacing*

*Ventricular Fibrillation/Cardiac Arrest:*

- *Protocol for emergency defibrillation*
- *Protocol for obtaining immediate anesthesia care and intubation in the cardiovascular catheterization laboratory*



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- *Protocol for initiation of standard or mechanical cardiopulmonary resuscitation (e.g., LUCAS device)*
- *Protocol for running a code including location of crash cart and roles of key players*

*Coronary Perforation:*

- *Protocol for immediate locations of echocardiography machine, supply of covered stents and/or coils and pericardiocentesis kit.*
- *Protocol for placement of covered stent or coils (including second access site, larger guide catheter, etc.)*
- *Protocol for obtaining emergency echocardiography*
- *Protocol for emergency pericardiocentesis*

*Contrast Reaction:*

- *Protocol for emergent treatment of contrast allergy*
- *Protocol for emergency treatment of anaphylactic/anaphylactoid reaction including IV fluids, IV steroids, and epinephrine (1 ml 1:10,000 epinephrine IV over 1 minute for life-threatening reactions)*
- *Protocol for obtaining immediate anesthesia care and intubation in the cardiovascular catheterization laboratory*

*Tamponade:*

- *Protocol for emergency pericardiocentesis*

*Sudden Cardiogenic Shock or Cardiac Arrest:*

- *Protocol for alerting cardiac surgery as needed for emergency CABG or ECMO (i.e., SHOCK TEAM alert, if available)*
- *Protocol for obtaining immediate anesthesia care and intubation in the cardiovascular catheterization laboratory*
- *Protocol for emergency IABP, Impella or peripheral ECMO*

*Emergency Transfers:*

- *Protocol for transferring patient to the OR for emergency surgical procedure*
- *Protocol for transferring patient to another hospital for emergency procedure*
- *Protocol for converting procedure to an emergency open procedure in a hybrid cardiovascular catheterization laboratory*

*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°;*



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*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.*

*1.8B TAVR Program[14, 62]*

| | |
|---|---|
| *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.*<br>• *Experience with, and management of, peripherally inserted cardiopulmonary bypass*<br>• *Experience with open retroperitoneal exposure of, and surgical intervention on, the iliac arteries*<br>• *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)*<br>*<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*<br>*Suitable training on devices to be used.*<br>*≥ 20 transcatheter mitral valve interventions/year (or ≥ 40 interventions every two years); and perform ≥ 300 PCIs per year[62]* |
| *Surgical program* | *25 total mitral valve procedures per year, of which at least 10 must be mitral valve repairs.*<br>*≥ 20 mitral valve surgeries per year (or ≥ 40 every two years)[62]* |
| *Data registry* | *All cases should be submitted to a national clinical database.* |
| *Existing programs* | *15 mitral (total experience)* |



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| | |
|---|---|
| | *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.*<br>*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*<br>*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* |

*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.*[6,33,34,35,62]



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*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*
- *Patient Foramen Ovale Closures for Stroke: initial procedure volumes of 7–50 cases to achieve a basic level of proficiency. And then >50 life-time structural or congenital catheter based interventions which includes a minimum of 25 procedures involving atrial septal interventions or 12 specific to PFO closure.*[64]
- *Patient Foramen Ovale / Atrial Septal Defect Closures >30 procedures that involve atrial septal interventions or > 15 PFO device closures over a 2 year period.* [64]

*In alignment with the current CMS National Coverage Determination (NCD) for reimbursement of TAVR:*

- *Facilities performing TAVR procedures for patients with acquired heart disease should perform ≥ 30 surgical aortic valve replacements (SAVRs)/year (or 60 over 2 years), ≥ 300 PCIs/year, and ≥ 50 TAVRs/year (or 100 over 2 years)*

*Facilities performing TMVR procedures for patients with acquired heart disease should include the following:*

- *≥ 20 transcatheter mitral valve interventions/year (or ≥ 40 interventions every two years); ≥ 20 mitral valve surgeries per year (or ≥ 40 every two years); and perform ≥ 300 PCIs per year.* [62]

*Facilities performing transcatheter edge-to-edge repair procedures such as MitraClip should include the following:*

- *2019 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional*

*Clinical competence guidelines state that to maintain proficiency while keeping complications at a low level, a minimum volume of 200 PCIs/year be achieved by all institutions.* [62] *Or for each operator a minimum PCI volume of 50/year is recommended, averaged over 2 years.*

*Operators performing Primary Percutaneous Coronary Intervention (PPCI, PCI in the setting of acute ST elevation myocardial infarction) procedures should include the following:*

- *11 PPCI/year and that institutions should perform 36 PPCI/year.* [62]

*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 Program

### STANDARD – QI Program

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

1.1.1C procedure/test appropriateness;

1.1.2C medical record completeness and timeliness;

1.1.3C safety;

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

1.1.5C technical quality and performance of the procedure; and

1.1.6C interpretive quality review.

*(See Guidelines on Page 77 for further recommendations.)*

### 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 review of the reports of QI evaluations and any corrective actions taken to address any deficiencies.



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

*1.1.1C 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 2C: Quality Improvement Measures

## STANDARD – General QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C through 2.1.6C. All metrics need to be measured for a minimum of four cases per procedure type, where applicable and be reviewed every six months.[1,2,3,6,62]

2.1.1C Procedure/Test Appropriateness

2.1.1.1C The facility must evaluate the appropriateness of the procedure performed and categorize as:

i. appropriate;
ii. may be appropriate;
iii. rarely appropriate / usually not appropriate; and
iv. not appropriate.

2.1.1.2C The facility must evaluate the appropriateness of the procedures based on criteria published and/or endorsed by professional medical organization(s).

Comment: The facility should develop a plan to track and address appropriateness of indications over time through longitudinal comparison and outcome measures.

*(See Guidelines on Page 80 for further recommendations.)*

2.1.2C Medical Record Completeness and Timeliness

2.1.2.1C The facility must evaluate the final report for completeness and timeliness as required by Standards 1.5B through 1.11B.

2.1.2.2C Final report completeness and timeliness must be measured for a minimum of four cases per procedure type and be reviewed every six months.

2.1.3C Safety

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

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

2.1.3.3C The QI Program must include assessment of the safety of the procedures being performed.

2.1.3.4C Safety must be measured for a minimum of four cases per procedure type and be reviewed every six months.

2.1.3.5C Areas that must be assessed include, but not limited to:

i. patient and personnel safety must be evaluated to include, but not limited to:

- accuracy of patient identification;
- medication safety;
- infection control measures; and



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- staff (occupational) and patient radiation exposure monitoring according to state regulations and published guidelines where appropriate; and [17,20,21,22,23,45]
- documentation of adverse technical events such as equipment or device failure.

2.1.3.6C Participation in a national registry for all patients is strongly recommended.

Comment: If resources allow; dedicated, trained personnel and/or processes to perform data abstraction, data entry, registry query and report generation/distribution should be considered.

2.1.4C Procedure Outcomes (including complications and any adverse events)

2.1.4.1C The QI program must include a process for documentation of complications with the goal to decrease complication.

2.1.4.2C Areas that must be assessed include, but not limited to:

i. all procedural complications including all serious adverse events;
ii. Procedure outcomes, including success rates and complications, should be documented and recorded. Data acquired from the QI process should be used to benchmark the complication rates and outcomes of both individual practitioners and the overall facility.
iii. 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.
iv. 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.
v. Outcomes data, which must be consistent with national benchmarks when available, must be used to improve processes and procedures (refer to Appendix C).
vi. 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.

2.1.5C Technical Quality and Performance of the Procedure

2.1.5.1C The QI Program must include an assessment of the image quality for the procedures being performed and have a process for documentation of complications with the goal to decrease complications.

2.1.5.2C The facility must evaluate the technical quality of the images obtained during the performance of procedures. The review must include, but not limited to, the evaluation of:

i. the clinical images for clarity of images and/or evaluation for suboptimal images or artifact;
ii. completeness of the study;
iii. adherence to the facility imaging acquisition protocols; and



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

2.1.5.3C 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 Page 80 for further recommendations regarding quality assessment of diagnostic coronary angiography.)*

2.1.6C Interpretive Quality Review

2.1.6.1C 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.

2.1.6.2C Anonymized peer review, or blinded review is required when only one interpreting physician is present in the facility.

2.1.6.3C 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.

## 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.*

*2.1.5C 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.

3.1.2C All major or minor complications referenced in guidelines (1.4.3.1B) must be reviewed during these meetings.

3.1.2.1C 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.

3.1.2.2C Complications not discussed in M&M conferences must be reviewed at QI meetings.

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

3.2.1C The Medical Director and medical staff must attend a minimum of one M&M conference per quarter, related to cardiovascular catheterization procedures.

3.2.2C All major Cardiovascular Catheterization Laboratory (CCL) and in-hospital complications should be reviewed at an M&M conference, held at least quarterly.[62]

3.2.2.1C In the case of a severe complication in the CCL, tools such as same-day or next-day debriefing, root-cause analysis and M&M case reviews should be implemented to optimize protocol to improve CCL readiness and patient outcomes.



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# Section 4C: Quality Improvement Documentation

## STANDARD – QI Documentation and Record Retention

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

4.1.1C the data for all of the QI measures above;

4.1.2C minutes from the QI meetings; and

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

4.2C The QI documentation must be maintained and available for all appropriate personnel to review.



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# Selected Bibliography


1. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. Patel, MR, Calhoon, JH, Dehmer, GJ, et al, *J Amer Coll Cardiol*, Mar 2017, 23391; DOI: 10.1016/j.jacc.2017.02.001. www.onlinejacc.org/content/69/17/2212
2. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Stable Ischemic Heart Disease: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. Wolk, M., et al., *J Amer Coll Cardiol*, 2014; 63(4):308-406. www.onlinejacc.org/content/63/4/380
3. Indications for Cardiac Catheterization and Intervention in Pediatric Cardiac Disease: A Scientific Statement from the American Heart Association. Feltes, TF, Bacha, E., Beekman, RH, et al., *Circulation*, 2011; DOI: 10.1161/CIR.0b013e31821b1f10. www.ahajournals.org/doi/full/10.1161/cir.0b013e31821b1f10
4. COCATS 4 Task Force 10: Training in Cardiac Catheterization. King, SB, Babb, JD, Bates, ER, et al., *J Amer Coll Cardiol*, 2015; 65(17):1844-1853. www.onlinejacc.org/content/65/17/1844
5. Task Force 3: Training in Diagnostic and Interventional Cardiac Catheterization: Endorsed by the Society for Cardiovascular Angiography and Interventions. Jacobs, AK, Babb, JD, Hirshfeld, JW, et al., *J Am Coll Cardiol*, 2008; 51(3):355-361. www.jacc.org/doi/10.1016/j.jacc.2007.11.011
6. 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. Bashore, TM, Balter, S, Barac, A, et al., *J Am Coll Cardiol*, 2012; 59(24):2221-2305. www.onlinejacc.org/content/59/24/2221
7. 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). Harold, JG, Bass, TA, Bashore, TM, et al., *J Am Coll Cardiol*, 2013; 62(4):357-396. www.onlinejacc.org/content/62/4/357
8. ACCF/AHA/SCAI 2007 Update of the Clinical Competence Statement on Cardiac 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 Update the 1998 Clinical Competence Statement on Recommendations for the Assessment and Maintenance of Proficiency in Coronary Interventional Procedures). King, SB, Aversano, T, Ballard, WL, et al., *J Am Coll Cardiol*, 2017; 50(1):82-108. www.onlinejacc.org/content/50/1/82
9. Task Force 3: Pediatric Cardiology Fellowship Training in Cardiac Catheterization Endorsed by the Society for Cardiovascular Angiography and Interventions. Armsby, LB, Vincent, RN, Foerster, SR, et al., *J Am Coll Cardiol*, 2015; 66(6):699-705. www.onlinejacc.org/content/66/6/699
10. Task Force 6: Pediatric Cardiology Fellowship Training in Adult Congenital Heart Disease. Stout, K, Valente, AM, Bartz, PJ, et al., *J Am Coll Cardiol*, 2015; 66(6):723-731. www.onlinejacc.org/content/66/6/723
11. Task Force 1: Training in Clinical Cardiology. Baughman, KL, Duffy, FD, Eagle, KA, et al., *J Am Coll Cardiol*, 2008; 51(3):339-348. www.jacc.org/doi/10.1016/j.jacc.2007.11.009
12. American Board of Internal Medicine Policies and Procedures for Certification. www.abim.org/Media/splbmcpe/policies-and-procedures.pdf
13. American Academy of Pediatrics Section on Cardiology and Cardiac Surgery, Guidelines for Pediatric Cardiovascular Centers. Moore, JWM, Beekman, RH, Case, CL, et al, *Pediatrics*, 2002; 109(3):544-551. pediatrics.aappublications.org/content/109/3/544
14. Multisociety (AATS, ACCF, SCAI, and STS) Expert Consensus Statement: Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part 1: Transcatheter Aortic Valve Replacement. Tommaso, CL, Bolman, RM, Feldman, T, et al., *J Am Coll Cardiol*, 2012; 59(22):2028-2042. www.onlinejacc.org/content/59/22/2028




*Return to Table of Contents*

15. SCAI/AATS/ACC/STS Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part II: Mitral Valve. Tommaso, CL, Fullerton, DA, Feldman, T, et al., *J Am Coll Cardiol*, 2014; 64(14):1515-1526. www.onlinejacc.org/content/64/14/1515

16. SCAI/AATS/ACC/STS Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part III: Pulmonic Valve. Hijazi, ZM, Ruiz, CE, Zahn, E, et al., *J Am Coll Cardiol*, 2015; 65(23):2556-2564. www.onlinejacc.org/content/65/23/2556

17. Radiation Safety Program for the Cardiac Catheterization Laboratory. Chambers, CE, Fetterly, KA, Holzer, R, et al., *Catheterization and Cardiovascular Interventions*, 2011; DOI 10.1002/ccd.22867 www.onlinelibrary.wiley.com/doi/10.1002/ccd.22867

18. AAPM Report No. 70 Cardiac Catheterization Equipment Performance Report of Task Group #17 Diagnostic X-ray Imaging Committee. Austin, BT, Balter, S, Clarke, GD, et al., Medical Physics Publishing, 2001; ISBN: 1-888340-28-2, ISSN: 0271-7344. www.aapm.org/pubs/reports/rpt_70.pdf

19. Quality Improvement Guidelines for Preventing Wrong Site, Wrong Procedure, and Wrong Person Errors: Application of the Joint Commission "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" to the Practice of Interventional Radiology. *J Vasc Interv Radiol*, 2008; 19:1145-1151. www.jvir.org/article/S1051-0443(08)00473-9/fulltext

20. FDA Code of Federal Regulations (CFR) Title 21 for system performance. 2014; (21)8. CFR - Code of Federal Regulations Title 21

21. Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study - Part II: Skin Dose. Miller, DL, Balter, S, Cole, PE, et al., *J Vasc Interv Radiol*, 2003; 15:919-926. www.jvir.org/article/S1051-0443(07)60435-7/pdf

22. Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study Part III: Dosimetric Performance of the Interventional Fluoroscopy Units. Balter, S, Schueler, BA, Miller, DL, et al, *J Vasc Interv*; 2004; 15:919-926. www.jvir.org/article/S1051-0443(07)60496-5/pdf

23. Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record. Miller, D., et. al., *J Vasc Interv Radiol*, 2004; 14:977-990. www.jvir.org/article/S1051-0443(11)01256-5/fulltext

24. SCAI Expert Consensus Update on Best Practices in the Cardiac Catheterization Laboratory. Aronow, HD, et. al, *Catheterization and Cardiovascular Interventions*, 2016; CCI-10-0399. scai.org/publications/clinical-documents/scai-expert-consensus-statement-best-practices-cardiac

25. SCAI Expert Consensus Statement for Advanced Training Programs in Pediatric and Congenital Interventional Cardiac Catheterization. Armsby, L, Beekman, RH, Benson, L, et al., *Catheterization and Cardiovascular Interventions*, 2014; 84: 779-784, DOI 10.1002/ccd 25550. www.onlinelibrary.wiley.com/doi/10.1002/ccd.25550/epdf

26. USFDA, Recommendation for Healthcare Professionals on Preventing Surgical Fires, U.S. Food and Drug Administration. www.fda.gov/media/83903/download

27. The Joint Commission, Preventing Surgical Fires, 2003; Issue 29. https://www.jointcommission.org/-/media/tjc/newsletters/sea-68-surgical-fire-prevention2-10-9-23-final.pdf

28. Operating Room Fire Safety. Hart, S., et al, *The Ochsner Journal*, 2011; 11:37- 42. www.ncbi.nlm.nih.gov/pmc/articles/PMC3096161/pdf/i1524-5012-11-1-37.pdf

29. Outline of Administrative Policies for Quality Assurance and Peer Review of Tissue Reactions Associated with Fluoroscopically-Guided Interventions. Balter, S., et al, NCRP Statement No. 11, December 31, 2014. www.ncrponline.org/wp-content/themes/ncrp/PDFs/Statement_11.pdf

30. Coronary Angiography in the Angioplasty Era; Projections with a Meaning. DiMario, C, Sutaria, N, *Heart*, 2005; 91:968-976. www.ncbi.nlm.nih.gov/pmc/articles/PMC5340896

31. Percutaneous Tricuspid Valve Replacement in Congenital and Acquired Heart Disease. Roberts, PA, Boudjemline, Y, Cheatham, JP, et al, *J Am Coll Cardiol*, 2011; 58(2):117-122. www.onlinejacc.org/content/58/2/117.full-text.pdf

32. AMERICAN ACADEMY OF PEDIATRICS Section on Cardiology and Cardiac Surgery: Guidelines for Pediatric Cardiovascular Centers. Moore, JWM, Beekman, RH, Case, CL, et al., *Pediatrics*, 2002; 109(3): 544-549. https://pediatrics.aappublications.org/content/109/3/544

33. Relationship between hospital procedure volume and complications following congenital cardiac catheterization: A report from the Improving Pediatric and Adult Congenital Treatment (IMPACT) registry. Jayaram, N, Spertus, JA, O'Byrne, ML, et al., *American Heart Journal*, 2017; 183: 118-128. www.ahjonline.com/article/S0002-8703(16)30217-4/abstract

34. Outcomes of PCI in Relation to Procedural Characteristics and Operator Volumes in the United States. Fanaroff, AC, Zakrovsky, MS, Dai, D, et al, *J Am Coll Cardiol*, 2017; 69(24): 2913- 2924. www.onlinejacc.org/content/69/24/2913



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35. EDITORIAL COMMENT: PCI Volume Benchmarks Still Adequate for Quality Assessment in 2017. Kumbhani, DJ, Nallamothu, BK, *J Am Coll Cardiol*, 2017; 69(24): 2926- 2928. www.onlinejacc.org/content/69/24/2925

36. Protection Against Cerebral Embolism During Transcatheter Aortic Valve Replacement. Kapadia, SR, Kodali, S, Makkar, R, et al., *J Am Coll Cardiol*, 2017, 69(4): 367-377. www.onlinejacc.org/content/69/4/367

37. 2012 ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement. Holmes, DR, Mack, MJ, Kaul, S, et al, *J Am Coll Cardiol*, 2012, 59(13): 1201-1254 www.onlinejacc.org/content/59/13/1200

38. 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary. Nishimura, RA, Otto, CM, Bonow, RO, et al., *Circulation*, 2014, 129:2440-2492. www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000029

39. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease. Nishimura, RA, Otto, CM, Bonow, RO, et al., *Circulation*, 2017, 135:1159-1195. www.ahajournals.org/doi/full/10.1161/cir.0000000000000503

40. 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults with Aortic Stenosis: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. Otto, CM, Kumbhani, DJ, Alexander, KP, et al, *J Am Coll Cardiol*, 2017; 69:1313-1346. www.jacc.org/doi/10.1016/j.jacc.2016.12.006

41. Defining Structural Heart Disease in the Adult Patient: Current Scope, Inherent Challenges and Future Directions. Steinberg, DH, Staubach, S, Frake, J, Sievert, H, *European Heart Journal*, 2010; 12:2-9. www.academic.oup.com/eurheartjsupp/article/12/suppl_E/E2/452925

42. Congenital Heart Defects in Adulthood. Diller, GP, Breithardt, G, Baumgartner, H, *Dtsch Arztebl Int*, 2011, 108(26): 452-459. www.ncbi.nlm.nih.gov/pmc/articles/PMC3139408/

43. ESC Guidelines for the management of grown-up congenital heart disease (new version 2010). Baungartner, H, Bongoeffer, P, DeGroot, NM, et al, *European Heart Journal*, 2010, 31(23): 2915-2957. www.ncbi.nlm.nih.gov/pubmed/20801927/

44. Task Force 1: the changing profile of congenital heart disease in adult life. Warnes, CA, Liberthson, RL, Danielson, GK et al, *J Am Coll Cardiol*, 2001; 37(5): 1170-1175. www.onlinejacc.org/content/37/5/1170

45. Radiation Safety in Children With Congenital and Acquired Heart Disease. Hill, KD, Frush, DP, Han, BK, Armstrong, AK, et al, *JACC Cardiovascular Imaging*, 2017; 10(7): 797-818. www.jacc.org/doi/abs/10.1016/j.jcmg.2017.04.003

46. ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory: A Report of the American College of Cardiology Clinical Quality Committee. Sanborn, TA, Tcheng, JE, et al, *J Am Coll Cardiol*, 2014; 63(23): 2591-2623. www.onlinejacc.org/content/63/23/2591

47. Classification for Assessing the Quality of Diagnostic Coronary Angiography. Généreux, P, Mehran, R, Leon, MB, et al, *J Invasive Cardiol*, 2017; Vol. 29: 1-4. pubmed.ncbi.nlm.nih.gov/28809722

48. Practice Advisory for the Prevention and Management of Operating Room Fires: An Updated Report by the American Society of Anesthesiologists Task Force on Operating Room Fires. Apfelbaum, JL, Caplan, RA, Connis, RT, et al, *Anesthesiology*, 2013; 118(2): 1-20. pubs.asahq.org/anesthesiology/article/118/2/271/13592/Practice-Advisory-for-the-Prevention-and

49. Cardiovascular Laboratory Service Design Guide. Department of Veterans Affairs – CFM. *ALERT*, 2016; 003C2B-SA-011: 1-15. www.cfm.va.gov/til/sAlert/sAlert011.pdf

50. SCAI/ACC/AHA Expert Consensus Document: 2014 Updated on Percutaneous coronary Intervention Without On-Site Surgical Backup. Dehmer, GJ, Blanenship, JC, Cilingiroglu, M, et al, *Circulation*, 2014; 129:2610-2626. www.ahajournals.org/doi/10.1161/CIR.0000000000000037

51. 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Levine, GN, Bates, ER, Blankenship, JC, et al, *Circulation*, 2015; 133:1135-1147. www.ahajournals.org/doi/full/10.1161/CIR.0000000000000336

52. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Levine, GN, Bates, ER, Blankenship, JC, et al, *J Am Coll Cardiol*, 2011; 58(24):e44-e122. www.jacc.org/doi/10.1016/j.jacc.2011.08.006

53. The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions. Dehmer GJ,



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Blankenship J, Wharton TP Jr, Seth A, Morrison DA, DiMario C, Muller D, Kellett M, Uretsky BF, *Catheter Cardiovasc Interv*. 2007; 69:471-8. www.onlinelibrary.wiley.com/doi/epdf/10.1002/ccd.21097

54. ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO, *J Am Coll Cardiol*, 2006; 47:e1-e121. www.onlinejacc.org/content/47/1/e1
55. Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery. Aversano, T, Lemmon, CC, Liu, L, *N Engl J Med*, 2012; 366:1792-802. www.nejm.org/doi/pdf/10.1056/NEJMoa1114540
56. Evaluation of the American College of Cardiology/American Heart Association and the Society for Coronary Angiography and Interventions Lesion Classification System in the Current "Stent Era" of Coronary Interventions (from the ACC-National Cardiovascular Data Registry). Krone RJ, Shaw RE, Klein LW, et al, *J Am Coll Cardiol*, 2003; 92:389-94. www.ajconline.org
57. 2021 ACC Expert Consensus Decision Pathway on Same-Day DischargeAfter Percutaneous Coronary Intervention, A Report of the American College of Cardiology Solution Set Oversight Committee. Rao, S., Vidovich, M., Gilchrist, I., et al, *J Am Coll Cardiol*, 2021; 77(6): 811-185. www.acc.org/latest-in-cardiology/ten-points-to-remember/2021/01/05/23/39/2021-acc-expert-same-day-discharge-pci
58. SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers. Box, L., Blankenship, J., Henry, T., et al, *Catheterization and Cardiovascular Interventions*. 2020;96:862–870. www.onlinelibrary.wiley.com/doi/epdf/10.1002/ccd.28991
59. SCAI Clinical Expert Consensus Statement on the Classification of Cardiogenic Shock. Baram, D., Grines, C., Bailey, S., et al, *Catheterization and Cardiovascular Interventions*;94:29–37. www.onlinelibrary.wiley.com/doi/epdf/10.1002/ccd.28329
60. SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Catheterization Laboratory: (Endorsed by the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencionista; Affirmation of Value by the Canadian Association of Interventional Cardiology–Association Canadienne de Cardiologie d'intervention). Naidu, S., Aronow, H., Box, L., et al,. *Catheterization and Cardiovascular Interventions*, 2016;88:407-423. www.onlinelibrary.wiley.com/doi/epdf/10.1002/ccd.26551
61. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 Appropriate Use Criteria for Diagnostic Catheterization. Patel, M., Bailey, S., Bonow, R., et al, *J Am Coll Cardiol*, 2012; 59:65-97. www.jacc.org/doi/10.1016/j.jacc.2012.03.003?articleid=1182705
62. SCAI Expert Consensus Update on Best Practices in the Cardiac Catheterization Laboratory, Naidu, S.S., Abbott, J.D., Bagai, J., et al, Catheter Cardiovasc Interv. Apr 2021 DOI: 10.1002/ccd.29744/ *Catheterization and Cardiovascular Interventions*. 2021;1–22. www.scai.org/publications/clinical-documents/scai-expert-consensus-update-best-practices-cardiac-catheterization
63. SCAI Expert Consensus Statement on Operator and Institutional Requirements for PFO Closure for Secondary Prevention of Paradoxical Embolic Stroke. Horlick, E, Kavinsky, CJ, Amin, Z, et al. *Catheterization and Cardiovascular Interventions*. 2019; 93: 859-874. onlinelibrary.wiley.com/doi/full/10.1002/ccd.28111



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# Appendix A

*Medical Staff Required Training and Experience*

Facilities must follow best practices to lower radiation exposure to patients, operator and cardiovascular catheterization staff.

1.1.3A through 1.7.1A and 1.10.1A Summary of methods to decrease radiation dose and exposure to patient and cardiovascular catheterization staff. [62]

i. Select low dose settings on fluoroscope, such as lower dose per frame, lower frame rate (4-7.5 frames per second (fps) for fluoroscopy, 7.5-15 fps for cine)
ii. Use "Fluoro Save" instead of cine when possible
iii. Use collimation to lower radiation dose and scatter to patient and staff
iv. Avoid working in steep angles and change working angles to "spread the dose"
v. Raise table height to decrease patient dose, and minimize distance between patient and detector to decrease patient dose and scatter to operator
vi. Use lower magnification (example 22 cm field of view (FOV) instead of 19 cm)
vii. Keep patient's extremities out of the beam path and away from the x-ray tube
viii. Maintain furthest possible distance from x-ray tube by using long tubing, especially for radial cases, and "taking a step back". Ensure proper use of moveable lead shields and under-table drapes.
ix. Consider moveable lead screens to protect CCL staff
x. Consider use of real-time radiation monitoring, radiation protection drapes and robotic PCI to lower operator radiation exposure
xi. Regular assessment and upgrading of equipment (hardware and/or software) to minimize radiation dose

<u>All medical staff member(s) must comply with national society training standards:</u>

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]
v. ACCF/AHA/SCAI 2007 Update of the Clinical Competence Statement on Cardiac 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 Update the 1998 Clinical Competence Statement on Recommendations for the Assessment and Maintenance of Proficiency in Coronary Interventional Procedures).[7]
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]



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

### *Facilities Performing Diagnostic Catheterization and Percutaneous Coronary Interventions (PCI) Without On-Site Cardiac Surgical Back-up*

Facilities without on-site cardiac surgical backup must comply with the following:

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.

**Facility Requirements for PCI Programs Without On-Site Cardiac Surgical Backup**:[7,50,51,52,53,54,55,56]

General Recommendations

i. Requisite support equipment must be available and in good working order to respond to emergency situations.
ii. Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.
iii. Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.
iv. The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.
v. Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤30 min and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery. Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral.
vi. Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data [via T-1 transmission line] as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.
vii. Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required. Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.
viii. Meticulous clinical and angiographic selection criteria for PCI (See section below labeled Recommendations for Off-Site Surgical Backup and Case Selection).
ix. Participation in a national data registry is recommended. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.
x. A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.
xi. Full service laboratories [both primary and elective PCI, with and without on-site cardiac surgery] performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high-volume center to enhance their skills.
xii. Geographic isolation exists if the emergency transport time to another facility is >30 min.



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xiii. Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.

xiv. As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.

STEMI Treatment Recommendations

i. Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including:
   - Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes.
   - A process for prehospital identification and activation.
   - Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center.
   - A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers.
   - Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.

ii. STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule. The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.

iii. STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.

iv. Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high-volume PCI facility to ensure good outcomes.

v. There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.

vi. Participation in the Mission Lifeline-approved data collection tool and ACTION Registry-Get with the Guidelines™ is recommended for the STEMI-Receiving Centers.

vii. They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan.

viii. Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis:
   a. door-to-first device time, non-transfer patients;
   b. STEMI Referral Hospital ED door-to-balloon (first device used) time;
   c. first medical contact to balloon inflation (first device used) time, non-transfer patients;
   d. first medical contact to balloon inflation (first device used) time, transfer patients;
   e. proportion of eligible patients receiving reperfusion therapy;
   f. proportion of eligible patients administered guideline-based class I therapies;
   g. proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization laboratory for intended primary PCI who:
      i. do not undergo acute catheterization because of misdiagnosis;
      ii. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 hours.
   h. in-hospital mortality.

**Personnel Requirements for PCI Programs Without On-Site Cardiac Surgical Backup**:[7,50,51,52,53,54,55,56]

Personnel Recommendations



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i. Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.

ii. Coronary care unit nursing staff must be experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications.

iii. Personnel should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.

iv. Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.

v. Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a two-year period) to maintain competency.

vi. Primary PCI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 primary PCI procedures per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.

vii. Facilities should develop internal review processes to assess operators performing <50 PCIs annually. Individual operator level volume is one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.

*Newly trained interventional cardiologists joining an established PCI program should be mentored by existing physicians until it is determined their skills, judgment and outcomes are acceptable*.

**Recommendations for Off-Site Surgical Backup and Case Selection**:[7,50,51,52,53,54,55,56]

Recommendations – Cardiologist – Cardiac Surgeon Interactions

i. Interventional cardiologists must establish a working relationship with cardiac surgeons at the receiving facility.

ii. Cardiac surgeons should have privileges at the referring facility to allow review of treatment options as time allows.

iii. Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis *(Heart Team approach) especially for the discussion of management of patients undergoing nonprimary PCI who have left main, three-vessel CAD or two-vessel CAD with involvement of the LAD or comorbidities such as diabetes, depressed LV function or complex anatomy*.

iv. Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.

v. Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at that time.

vi. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.

vii. Interventional cardiologist should be familiar with and have immediate access to appropriate life support devices, such an intraaortic balloon pumps, and should be qualified for handling emergencies such as pericardial tamponade and embolization.

viii. Hospital administrations from both facilities endorse the transfer agreement.

ix. Transferring physicians obtain consent for surgery from patients or appropriate surrogates.

x. Initial informed consent for PCI discloses that the procedure is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery, should state that a written plan for transfer exists, should describe the risks associated with transfer to another facility, and should describe alternatives to care in this setting*. Consent for PCI should be obtained before the procedure and before any sedatives are given. Consent for PCI obtained while the patient is on the table is not informed consent and is unacceptable in non-emergency situations*.

Recommendations - Case Selection and Management

i. Avoid intervention with:



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a. >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired.
b. Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography.
c. Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms).
d. Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI.
e. Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.
f. Chronic total occlusion.

*The management of patients with STEMI resuscitated from sudden cardiac death is complex, and decisions about the need for immediate PCI with or without therapeutic hypothermia or possible transfer to a tertiary facility for treatment should be individualized.*

ii. Emergency transfer for coronary bypass surgery patients with:

a. High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support.
b. Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.

**Patient and Lesion Characteristics That Could Be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery**:[7,50,51,52,53,54,55,56]

i. High-risk patients:

a. decompensated congestive heart failure (Killip Class ≥3) without evidence for active ischemia;
b. recent (<8 weeks) cerebrovascular accident;
c. advanced malignancy;
d. known clotting disorders;
e. LVEF ≤30%;
f. chronic kidney disease (creatinine >2.0 mg/dL or creatinine clearance <60 mL/min);
g. serious ongoing ventricular arrhythmias;
h. patients with left main stenosis (>50% diameter) or three-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal or mid segments of all major epicardial coronary arteries), treatment of any or all stenoses. Scoring systems, such as SYNTAX, may be useful in defining the extent of disease and type of revascularization procedure;
i. patients with a single-target lesion that jeopardizes an extensive amount of myocardium;
j. patients undergoing intervention on the last remaining conduit to the heart.

ii. High-risk lesions:

a. unprotected left main stenosis;
b. diffuse disease (>20 mm in length);
c. extremely angulated segment (>90%) or excessive proximal or in-lesion tortuosity;
d. more than moderate calcification of a stenosis or proximal segment;
e. inability to protect major side branches;
f. degenerated older vein grafts with friable lesions;
g. substantial thrombus in the vessel or at the lesion site;
h. any other feature that could, in the operator's judgment, impede successful stent deployment;
i. anticipated need for rotational or other atherectomy device, cutting balloon or laser.

*The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine level increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.*



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iii. Strategy for surgical backup based on lesion and patient risk:

a. high-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery;
b. high-risk patients with nonhigh-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary;
c. non-high-risk patients with high-risk lesions require no additional precautions;
d. non-high-risk patients with nonhigh-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.



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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);
iii. transposition of the great arteries (d-TGA or l-TGA);
iv. coarctation of the aorta (CoA);



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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 and The Joint Commission requirements 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 and/or contrast in the container is required. For all medication containers, not on a sterile field, the medication and/or contrast 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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# Artificial Intelligence (AI) Guidance Document

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

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

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



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