IAC
INTERSOCIETAL ACCREDITATION COMMISSION
CARDIAC ELECTROPHYSIOLOGY

IAC Standards and Guidelines for Cardiac Electrophysiology Accreditation

Accreditation Standards

AUGUST 2025

Introduction

The Intersocietal Accreditation Commission (IAC) is a non-profit organization that accredits facilities that perform cardiac electrophysiology procedures. These procedures include, but are not limited to: electrophysiology testing, ablation, device implantation, extraction of chronically implanted transvenous pacing and defibrillator leads, left atrial appendage occlusion (LAAO) by device and post-procedural onsite and longitudinal remove monitoring of implantable devices. 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 cardiac electrophysiology 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 cardiac electrophysiology procedures by ensuring that the facility meets benchmarks for quality based on resources, training and outcomes. Cardiac electrophysiology procedures and/or post-procedural onsite and longitudinal remote monitoring of implantable devices may be appropriately performed for many indications related to the diagnosis and treatment of heart rhythm disorders.[1] The outcome benchmarks used in this program are intended to be applied only to cases treated for indications related to cardiac electrophysiology testing, ablation, device implantation, extraction of chronically implanted transvenous pacing and defibrillator leads and/or post-procedural onsite and longitudinal remote monitoring of implantable devices. A facility that meets the outcome benchmarks for these most common indications will most likely provide adequate outcomes for cardiac electrophysiology procedures and onsite and longitudinal remote monitoring of implantable devices performed for less common indications.

A facility performing cardiac electrophysiology procedures to include; cardiac electrophysiology testing, ablation, device implantation and extraction of chronically implanted transvenous pacing and defibrillator leads must provide the appropriately credentialed staff, equipment, policies and procedures. All personnel using equipment associated with cardiac electrophysiology procedures and/or post-procedural onsite and longitudinal remote monitoring of implantable devices must be able to demonstrate familiarity and proficiency with the setup, operation, and characteristics of the equipment employed at their site.

Each facility must have a Medical Director and a Technical Manager and/or Nurse Manager. The facility may be comprised of dedicated and/or shared equipment and personnel resources (e.g., a dedicated EP laboratory and personnel, a cardiac catheterization 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 cardiac electrophysiology 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 cardiac electrophysiology 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 cardiac electrophysiology and/or post-procedural onsite and longitudinal remote monitoring of implantable devices. It is also designed to be used as an educational tool to improve the overall quality of the facility.

Facilities may apply for a combination of procedure-based interventions and/or post-procedural onsite and longitudinal remote monitoring of implantable devices.

The following are the specific areas of cardiac electrophysiology for which accreditation may be obtained:

- Device Implantation
- Testing and Ablation
- Chronic Lead Extraction
- Left Atrial Appendage Occlusion (LAAO) by Device
- Device Clinic

Facilities may apply for device implantation and device clinic accreditation individually; however, testing and ablation, chronic lead extraction and left atrial appendage occlusion (LAAO) by device must be in combination with device implantation.

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 facilities performing heart rhythm management. 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 below, the facility, including all staff, must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

Part A: Organization

Section 1A: Personnel and Supervision

STANDARD – Medical Director

1.1A The Medical Director must be a licensed physician.

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. certification by the American Board of Internal Medicine (ABIM) or American Osteopathic Board of Internal Medicine (AOBIM) in clinical cardiac electrophysiology (CCEP);
ii. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac rhythm device therapy (Certified Cardiac Device Specialist [CCDS] – Physician); or
iii. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac electrophysiology (Certified Electrophysiology Specialist [CEPS] – Physician [separate exams for adult and pediatric/congenital practice]).

1.1.1.2A Level III training in cardiac electrophysiology.[2]

1.1.1.3A For pediatric cardiac electrophysiology, board certified in his/her specialty:

i. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac rhythm device therapy (Certified Cardiac Device Specialist [CCDS] – Physician); or
ii. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac electrophysiology (Certified Electrophysiology Specialist [CEPS] – Physician [separate exams for adult and pediatric/congenital practice]).

1.1.1.4A For device implantation only facilities, physicians must meet at least one training experience pathway as outlined in Standards 1.1.1.1A, 1.1.1.2A and 1.1.1.3A or one of the following:

i. Level II training in cardiac electrophysiology;[2]
ii. certification by the American Board of Thoracic Surgery (ABTS) in thoracic surgery specializing in cardiac or cardiovascular surgery and/or congenital cardiac surgery subspecialty; or
iii. certification by the American Board of Surgery (ABS) in thoracic surgery.

1.1.1.5A For device clinics, physicians must meet at least one training experience pathway as outlined in Standards 1.1.1.1A, 1.1.1.2A, 1.1.1.3A and 1.1.1.4A or one of the following:

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i. Level II training in Cardiac Electrophysiology;

ii. Cardiac Device Remote Monitoring Specialist (CDRMS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

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. The 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 cardiac electrophysiology 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 cardiac electrophysiology procedures performed in the facility.

1.1.2.6A For device clinics, demonstrating familiarity with equipment associated with post-procedural onsite and longitudinal remote monitoring of implantable devices 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 25 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 heart rhythm disorders that includes but is not limited to content that is directly related to the performance of cardiac electrophysiology procedures and/or heart rhythm disorders every three years. With the exception of device clinic accreditation, radiation safety training must be part of the CME and not be less than one hour of the 15 hours required (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CME requirement.). If the Medical Director performs these procedures, he/she must meet the qualifications and maintenance of qualifications of the medical staff.

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

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

ii. certification by the American Board of Internal Medicine (ABIM) or American Osteopathic Board of Internal Medicine (AOBIM) in clinical cardiac electrophysiology;

iii. certification by the American Board of Pediatrics (ABP) in pediatric cardiology;

iv. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac rhythm device therapy (Certified Cardiac Device Specialist [CCDS] – Physician);

v. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac electrophysiology (Certified Electrophysiology Specialist [CEPS] – Physician [separate exams for adult and pediatric/congenital practice]);

vi. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac device remote monitoring (Cardiac Device Remote Monitoring Specialist [CDRMS] – Allied Professional).

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

STANDARD – Medical Staff

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

1.2.1A Medical Staff Required Training and Experience

The medical staff must demonstrate an appropriate level of training and experience by meeting one or more of 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 clinical cardiac electrophysiology;

ii. certification by the American Board of Internal Medicine (ABIM) or American Osteopathic Board of Internal Medicine (AOBIM) in clinical cardiac electrophysiology;

iii. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac rhythm device therapy (Certified Cardiac Device Specialist [CCDS] – Physician); or

iv. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac electrophysiology (Certified Electrophysiology Specialist [CEPS] – Physician [separate exams for adult and pediatric/congenital practice]).

1.2.1.2A Level III training in cardiac electrophysiology.[28]

1.2.1.3A For pediatric cardiac electrophysiology, all medical staff should be board certified in his/her specialty:

i. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac rhythm device therapy (Certified Cardiac Device Specialist [CCDS] – Physician); or

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ii. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac electrophysiology (Certified Electrophysiology Specialist [CEPS] – Physician [separate examinations for adult and pediatric/congenital practice]).

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.

1.2.1.4A For device implantation only facilities, physicians must meet at least one training experience pathway as outlined in Standards 1.1.1.1A, 1.1.1.2A and 1.1.1.3A or one of the following:

i. Level II training in cardiac electrophysiology;[2]
ii. certification by the American Board of Thoracic Surgery (ABTS) in thoracic surgery specializing in cardiac or cardiovascular surgery and/or congenital cardiac surgery subspecialty; or
iii. certification by the American Board of Surgery (ABS) in thoracic surgery.

1.2.1.5A All physicians (including the Medical Director) performing cardiac electrophysiology 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.

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

i. have performed a minimum of 150 intracardiac, catheter-based ablation procedures or device-related procedures during training and/or in the first two years after completion of training, or in the previous three years of practice;
ii. have completed training and practiced EP/pacing for at least two years after completion of training; and
iii. have demonstrated at least 75 percent of clinical practice devoted to heart rhythm disorders to include the following:
    - a minimum of 300 intracardiac, catheter-based ablation procedures or device-related procedures during training and/or in the first two years after completion of training, or in the previous three years of practice.

1.2.1.7A For device clinics, physicians must meet at least one training experience pathway as outlined in Standards 1.2.1.1A, 1.2.1.2A, 1.2.1.3A, 1.2.1.4A, 1.2.1.5A and 1.2.1.6A or one of the following:

i. Level II training in cardiac electrophysiology;[2]
ii. Cardiac Device Remote Monitoring Specialist (CDRMS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE);
iii. 6 months of experience in reviewing transmissions/interrogations and/or vendor device transmission/interrogation training.

Comment: 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 cardiac electrophysiology procedures. Refer to Appendix A for currently acceptable national society training standards.

Comment: Operators performing left atrial appendage occlusion (LAAO) by device or chronic lead extraction must meet training requirements appropriate to the procedure being performed.

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1.2.2A Medical Staff Responsibilities

The medical staff is responsible for performing the evaluation, management and treatment of heart rhythm disorders. 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.

1.2.2.3A Demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the cardiac electrophysiology procedures performed in the facility.

1.2.2.4A For device clinics, demonstrating familiarity with equipment associated with post-procedural onsite and longitudinal remote monitoring of implantable devices performed in the facility.

(See Guidelines on Page 25 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 heart rhythm disorders that includes but is not limited to content that is directly related to the performance of cardiac electrophysiology procedures and/or heart rhythm disorders every three years. With the exception of device clinic accreditation, radiation safety training must be part of the CME and not be less than one hour of the 15 hours required (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CME requirement).

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

i. completion of an Accreditation Council for Graduate Medical Education (ACGME) approved (or similarly recognized) residency or fellowship;
ii. attaining certification by the American Board of Internal Medicine (ABIM) or American Osteopathic Board of Internal Medicine (AOBIM) in clinical cardiac electrophysiology;
iii. certification by the American Board of Pediatrics (ABP) in pediatric cardiology;
iv. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac rhythm device therapy (Certified Cardiac Device Specialist [CCDS] – Physician);
v. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac electrophysiology (Certified Electrophysiology Specialist [CEPS] – Physician [separate examinations for adult and pediatric/congenital practice]);
vi. certification by the International Board of Heart Rhythm Examiners (IBHRE) in cardiac device remote monitoring (Cardiac Device Remote Monitoring Specialist [CDRMS] – Allied Professional).

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

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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 Cardiac Electrophysiology Specialist (RCES) with the Cardiovascular Credentialing International (CCI); Certified Cardiac Device Specialist (CCDS) - Allied Professional, Certified Electrophysiology Specialist (CEPS) - Allied Professional or Cardiac Vascular Invasive Specialist (CVIS).

1.3.1.2A For Nurse Managers actively participating in cardiac electrophysiology procedures:

i. at least six months of critical care and/or emergency room nursing is recommended.

1.3.1.3A For adult cardiac electrophysiology:

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

1.3.1.4A For pediatric cardiac electrophysiology:

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 cardiac electrophysiology 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;

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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; and

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

(See Guidelines on Page 25 for further recommendations.)

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 heart rhythm disorders that includes, but is not limited to, content that is directly related to the performance of cardiac electrophysiology procedures, heart rhythm disorders, cardiovascular assessment and/or patient management every three years. Radiation safety training must be part of the CE and not be less than one hour of the 15 hours required (A facility-based radiation safety program, which provides a minimum of one hour of training every three years will satisfy the radiation safety CME 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 if CEPS held CE (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]). 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, CCDS, CEPS or CVIS) within the three years prior to the application date, the CE requirement will be considered fulfilled.

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

STANDARD – Technical Manager

1.4A The manager of the technical and nursing staff must be 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 at least one of the following criteria:

i. Registered Cardiac Electrophysiology Specialist (RCES) with the Cardiovascular Credentialing International (CCI);

ii. Registered Cardiovascular Invasive Specialist (RCIS) with the Cardiovascular Credentialing International (CCI);

iii. Certified Electrophysiology Specialist (CEPS) Allied Professional with the International Board of Heart Rhythm Examiners (IBHRE); or

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iv. Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

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);
ii. Cardiac-Interventional Radiography RT (CI);
iii. Certified Electrophysiology Specialist (CEPS) Allied Professional with the International Board of Heart Rhythm Examiners (IBHRE); or
iv. Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

1.4.1.3A A Registered Technologist in Radiological Technology (RTR) with the Canadian Association of Medical Radiation Technologists (CAMRT) meeting one or more of the following criteria:

i. Certified Electrophysiology Specialist (CEPS) Allied Professional with the International Board of Heart Rhythm Examiners (IBHRE); or
ii. Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

1.4.1.4A An allied professional meeting one or more of the following criteria:

i. Certified Electrophysiology Specialist (CEPS) Allied Professional with the International Board of Heart Rhythm Examiners (IBHRE); or
ii. Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

1.4.1.5A A registered specialist with the Cardiovascular Credentialing International (CCI) or a Registered Radiologic Technologist [RT(R)] with American Registry of Radiologic Technologists (ARRT) or a Registered Technologist in Radiological Technology (RTR) with the Canadian Association of Medical Radiation Technologists (CAMRT) with a minimum of five years of experience performing cardiac electrophysiology procedures. A letter from the Medical Director or supervising physician verifying the training, experience and competency in performance and supervision of cardiac electrophysiology procedures is required.

Comment: If the Technical Manager applying under pathway 1.4.1.5A 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, 1.4.1.2A, 1.4.1.3A or 1.4.1.4A.

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 cardiac electrophysiology procedures;

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

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

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

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

1.4.2.8A demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the cardiac electrophysiology procedures performed in the facility.

(See Guidelines on Page 25 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 heart rhythm disorders that includes, but is not limited to, content that is directly related to the performance of cardiac electrophysiology procedures, heart rhythm disorders 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 CME requirement.).

1.4.3.2A All CE hours must be approved (i.e., Recognized Continuing Education Evaluation Mechanism [RECEEM], Cardiovascular Credentialing International [CCI]-Cardiovascular CEU, Alliance of Cardiovascular Professionals [ACVP]-CEU, American Registry of Radiologic Technologists [ARRT]-Category A, American Society of Radiologic Technologists [ASRT], American Medical Association [AMA], American Nurses Credentialing Center [ANCC]-Category I).

Comment: If the Technical Manager has successfully attained an appropriate technical credential [CCDS, CEPS, RCES, 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.

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

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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 Cardiac Electrophysiology Specialist (RCES) with the Cardiovascular Credentialing International (CCI); Certified Cardiac Device Specialist (CCDS) - Allied Professional, Certified Electrophysiology Specialist (CEPS) - Allied Professional or Cardiac Vascular Invasive Specialist (CVIS).

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

1.5.1.3A Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) certification are required.

1.5.1.4A For pediatric cardiac electrophysiology:

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

1.5.2A Nurse(s) Responsibilities

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

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

1.5.2.2A administering and monitoring moderate sedation;

1.5.2.3A performing cardiovascular assessment;

1.5.2.4A knowing relevant radiation safety;

1.5.2.5A monitoring and assessing clinical status of patient;

1.5.2.6A cardiovascular and hemodynamic monitoring and management;

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

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

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

(See Guidelines on Page 25 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 heart rhythm disorders that includes, but is not limited to, content that is directly related to the performance of cardiac electrophysiology procedures, heart rhythm disorders, 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 CME requirement.).

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1.5.3.2A All CE hours must be American Nurses Credentialing Center (ANCC) approved and/or obtain appropriate CE if CEPS held CE (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]). 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, RCES, CCDS, CEPS or CVIS) within the three years prior to the application date, the CE requirement will be considered fulfilled.

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

STANDARD – Technical Staff

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

1.6.1A Technologist(s) Required Training and Experience

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

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

i. Registered Cardiac Electrophysiology Specialist (RCES) with the Cardiovascular Credentialing International (CCI);
ii. Registered Cardiovascular Invasive Specialist (RCIS) with the Cardiovascular Credentialing International (CCI);
iii. Certified Electrophysiology Specialist (CEPS) Allied Professional with the International Board of Heart Rhythm Examiners (IBHRE); or
iv. Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

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);
iii. Certified Electrophysiology Specialist (CEPS) Allied Professional with the International Board of Heart Rhythm Examiners (IBHRE); or
iv. Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

1.6.1.3A A Registered Technologist in Radiological Technology (RT[R]) with the Canadian Association of Medical Radiation Technologists (CAMRT) meeting one or more of the following criteria:

i. Certified Electrophysiology Specialist (CEPS) Allied Professional with the International Board of Heart Rhythm Examiners (IBHRE); or
ii. Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

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1.6.1.4A An allied professional meeting one or more of the following criteria:

i. Certified Electrophysiology Specialist (CEPS) Allied Professional with the International Board of Heart Rhythm Examiners (IBHRE); or

ii. Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

1.6.1.5A A registered specialist with the Cardiovascular Credentialing International (CCI) or a Registered Radiologic Technologist [RT(R)] with American Registry of Radiologic Technologists (ARRT) or a Registered Technologist in Radiological Technology (RTR) with the Canadian Association of Medical Radiation Technologists (CAMRT) with a minimum of one year of full-time equivalent experience as a cardiac electrophysiology technologist/specialist under the direct supervision of personnel meeting pathway 1.6.1.1A or 1.6.1.2A or 1.6.1.3A 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.

1.6.1.6A Completion of 12 months full-time (35 hours/week) clinical cardiac electrophysiology experience assisting in cardiac electrophysiology 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, cardiac electrophysiology 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;

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;

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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 be 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 cardiac electrophysiology:

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 cardiac electrophysiology procedures performed in the facility.

(See Guidelines on Page 25 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 heart rhythm disorders that includes but is not limited to content that is directly related to the performance of cardiac electrophysiology procedures, heart rhythm disorders 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 CME requirement.).

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

Comment: If the technologist staff member has successfully attained an appropriate technical credential [CCDS, CEPS, RCES, RCIS, RT(CI) or RT(CV)] within the three years prior to the application date, the CE requirement will be considered fulfilled.

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

STANDARD – Advanced Practice Providers

1.7A An advanced practice provider(s) works under the direction of the Medical Director or medical staff member who is listed in the application. The advanced practice provider must be a licensed professional who possesses knowledge in the treatment and performance of cardiac electrophysiology procedures and/or heart rhythm disorders 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.

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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 cardiac electrophysiology testing and ablation 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 cardiac device implantation 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 chronic lead extraction procedures, supervised participation in the active care of a minimum of 20 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.

iv. If assisting left atrial appendage occlusion (LAAO) by device procedures, supervised participation in the active care of a minimum of 20 cases over the previous three years is suggested (but not required) and must be documented, if claimed.

(See Guidelines for Standard 1.10B for further recommendations.)

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 cardiac electrophysiology 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;

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ix. monitoring, assessing and managing of emergency care to include Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) in facilities performing Pediatric Cardiac Electrophysiology 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 cardiac electrophysiology testing, ablation, device implantation and chronic lead extraction (when required) and left atrial appendage occlusion (LAAO) by device (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 cardiac electrophysiology procedures performed in the facility.

(See Guidelines on Page 25 for further recommendations.)

1.7.3A Provisional Advanced Practice Providers:

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

1.7.4A Continuing Education (CE) Requirements:

1.7.4.1A The advanced practice provider must obtain a minimum of 15 credit hours or dedicated CME for advanced practice providers relevant to heart rhythm disorders that includes, but is not limited to, content that is directly related to the performance of cardiac electrophysiology procedures, heart rhythm disorders, 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 CME requirement.).

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

1.7.4.2A 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]).

1.7.4.3A Documentation of CE credits must be kept on file and available for inspection.

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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, Nurse Manager, Technical Manager or Device Clinic 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 technical assistants;

1.8.1.3A clerical and administrative assistants;

1.8.1.4A computer support staff; or

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

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);

1.9.1.3A 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 for the performance of the procedures 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 in Medicine (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

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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.

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.

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.

1.10.2.10A It is recommended that the medical physicist observe at least one (cardiac electrophysiology) procedure with diagnostic imaging including fluoroscopy per year.

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1.10.3A Continuing Education (CE) Requirements

1.10.3.1A The medical physicist must obtain at least 15 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.

STANDARD – Device Clinic Manager

1.11A 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.

1.11.1A Device Clinic Manager Required Training and Experience

1.11.1.1A The Device Clinic 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. Doctor of Nursing Practice (DNP)

vi. In addition to the credential of RN, the individual may acquire one or more of the following:

- Certified Cardiographic Technician (CCT) with the Cardiovascular Credentialing International (CCI);
- Certified Rhythm Analysis Technician (CRAT) with the Cardiovascular Credentialing International (CCI);
- Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE);
- Cardiac Device Remote Monitoring Specialist (CDRMS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

vii. Physician Assistant (PA)

viii. American College of Sports Medicine Certified Clinical Exercise Physiologist (ACSM-CEP) with the American College of Sports Medicine (ACSM)

1.11.1.2A For Device Clinic Managers:

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i. Demonstrate familiarity with equipment associated with post-procedural onsite and longitudinal remote monitoring of implantable devices performed in the facility.

1.11.1.3A For adult and pediatric onsite device clinics:

i. Basic Life Support (BLS)

1.11.2A Device Clinic Manager Responsibilities

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

1.11.2.1A the day-to-day operations of the facility;

1.11.2.2A management of post-procedural care and remote monitoring areas;

1.11.2.3A direct participation in the observation and care of patients post-procedural onsite and longitudinal remote monitoring of implantable devices, to include telehealth;

1.11.2.4A application of institutional guidelines for patient monitoring, medication management, implantable device management, remote monitoring and patient safety;

1.11.2.5A managing staff competencies and proficiency in performing tasks required for post-procedural onsite and longitudinal remote monitoring of implantable devices;

1.11.2.6A the delegation, when necessary, of specific responsibilities to the device clinic staff;

1.11.2.7A verification of documentation of proper training and, at least annually, assessment of the competence of device clinic staff who report to the Device Clinic Manager; and

1.11.2.8A demonstrating familiarity with the setup and operation of remote monitoring telehealth technologies.

1.11.3A Continuing Education (CE) Requirements

1.11.3.1A The Device Clinic Manager must obtain at least 15 hours of accredited CE relevant to device management and remote monitoring that includes, but is not limited to, content that is directly related to device management and remote monitoring, telehealth security, telehealth technologies, heart rhythm disorders, cardiovascular assessment and/or patient management every three years.

1.11.3.2A All CE hours must be approved (i.e., American Nurses Credentialing Center [ANCC-Category I], AMA Category I) and/or the device clinic staff member must obtain appropriate CE if CEPS held CE (i.e., Recognized Continuing Education Evaluation Mechanism [RECEEM], Cardiovascular Credentialing International [CCI]- Cardiovascular CEU, Alliance of Cardiovascular Professionals [ACVP] -CEU, American Medical Association [AMA]).

Comment: If the Device Clinic Manager has successfully attained an appropriate specialty certification (NP-C, PA, ACSM-CEP, ACSM, CNS, CCT, CCDS, CRAT, or CDRMS) within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.11.3.3A Documentation of CE credits must be kept on file and available for inspection.

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STANDARD – Device Clinic Staff

1.12A Device clinic staff at the facility must meet the following qualifications:

1.12.1A Device Clinic Staff Required Training and Experience

1.12.1.1A When appropriate, the device clinic staff 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)
v. In addition to the credential of RN, the individual may acquire one or more of the following:
- Certified Cardiographic Technician (CCT) with the Cardiovascular Credentialing International (CCI);
- Certified Rhythm Analysis Technician (CRAT) with the Cardiovascular Credentialing International (CCI);
- Certified Cardiac Device Specialist (CCDS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE);
- Cardiac Device Remote Monitoring Specialist (CDRMS) Allied Professional with International Board of Heart Rhythm Examiners (IBHRE).

vi. Physician Assistant (PA)
vii. American College of Sports Medicine Certified Clinical Exercise Physiologist (ACSM-CEP) with the American College of Sports Medicine (ACSM)
viii. Cardiac Device Remote Monitoring Specialist
ix. Allied professional with one of the following:
- a minimum of an Associate Degree in a medical field with at least one year of CIED remote monitoring or in person evaluations; or
- a minimum of two years of experience with CIED remote monitoring or in person evaluation.

1.12.1.2A At least six months of device management, cardiac rhythm analysis and remote monitoring is recommended.

1.12.1.3A For adult device clinics:

i. Basic Life Support (BLS); and
ii. Advanced Cardiac Life Support (ACLS) certification is recommended for those performing in person evaluation.

1.12.1.4A For pediatric device clinics:

i. Basic Life Support (BLS); and
ii. Pediatric Advanced Life Support (PALS) is recommended for those performing in person evaluation.

1.12.2A Device Clinic Staff Responsibilities

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The device clinic staff responsibilities may include, but are not limited to:

1.12.2.1A reporting to the Device Clinic Manager;

1.12.2.2A performing cardiovascular assessment;

1.12.2.3A monitoring and assessing clinical status of patient;

1.12.2.4A cardiovascular, hemodynamic, and diagnostic monitoring and management;

1.12.2.5A manage tasks required for post-procedural onsite and longitudinal remote monitoring of implantable devices;

1.12.2.6A monitoring, assessing, and managing of emergency care to include Basic Life Support in facilities performing post-procedural onsite and longitudinal remote monitoring of implantable devices;

Comment: Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) is recommended.

1.12.2.7A advising patient care team and treating patient appropriately;

1.12.2.8A demonstrating familiarity and proficiency with the setup and operation of all equipment associated with post-procedural onsite and longitudinal remote monitoring of implantable devices performed in the facility;

1.12.2.9A demonstrating familiarity with the setup and operation of remote monitoring telehealth technologies; and

1.12.2.10A providing patient and family education on CIED functionality, management and follow up.

1.12.3A Continuing Education (CE) Requirements

1.12.3.1A The device clinic staff must obtain at least 15 hours of accredited CE relevant to device management and remote monitoring that includes, but is not limited to, content that is directly related to device management and remote monitoring, telehealth security, telehealth technologies, heart rhythm disorders, cardiovascular assessment and/or patient management every three years.

1.12.3.2A All CE hours must be American Nurses Credentialing Center (ANCC) approved and/or obtain appropriate CE if CEPS held CE (i.e., Recognized Continuing Education Evaluation Mechanism [RECEEM], Cardiovascular Credentialing International [CCI]-Cardiovascular CEU, Alliance of Cardiovascular Professionals [ACVP]-CEU, American Medical Association [AMA]).

Comment: If the device clinic staff member has successfully attained an appropriate specialty certification (NP-C, PA, ACSM-CEP, ACSM, CNS, CCT, CCDS, CRAT, or CDRMS) within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.12.3.3A Documentation of CE credits must be kept on file and available for inspection.

STANDARD – Information Technology Officer / Representative

1.13A An information technology officer / representative must be identified for areas that contain and/or interface with the affected processes for the device clinic and remote monitoring.

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1.13.1A Information Technology Officer / Representative(s) Responsibilities

The responsibilities may include, but are not limited to:

1.13.1.1A Performing initial and annual surveys for data transmission and interrogation equipment and network performance evaluation including:

i. information system risk assessment to include compliance with state and federal requirements and guidelines;

- identification of individual(s) responsible for remediation of discrepancies/deficiencies; and
- maintain a current listing or catalog of state requirements.

ii. a current list of information technology (IT)/information security requirement sets the facility must meet;

iii. system quality control management;

iv. analyze all device manufacturer data interrogation and data management systems and provide appropriate recommendations;

v. appropriate networking of device interrogation rooms and equipment used to interrogate and manage device data; and

vi. other.

1.13.1.2A Providing a written summary of all assessment and evaluation criteria performed.

1.13.1.3A Providing guidance for any patient data management issues.

1.13.1.4A Providing Protected Health Information (PHI) data management and safety training for facility physicians and staff as required.

1.13.1.5A Other personnel, under the supervision and deemed by the information technology officer / representative as competent to perform the assigned tasks, may assist in the collection of data. The information technology officer / representative must review and approve all such data and remains personally responsible for the performance quality of the assigned tasks.

1.13.1.6A It is recommended that the information technology specialist(s) observe post-procedural onsite CIED interrogation, monitoring, data transmission and storage performed in the facility.

Section 1A: Personnel and Supervision *Guidelines*

1.1.2A, 1.2.2A, 1.3.2A, 1.4.2A, 1.5.2A, 1.6.2A and 1.7.2A	*Personnel performing and/or assisting electrophysiology testing and ablation and /or device implantation and/or extraction of chronically implanted transvenous pacing and defibrillator leads should comply with training requirements as listed in the Heart Rhythm Society Expert Consensus Statement on Electrophysiology Laboratory Standards: Process, Protocols, Equipment, Personnel and Safety[11] and Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management[10].*

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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 space requirements include, but are not limited to:

(See Guidelines on Page 33 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.

(See Guidelines on Page 33 for further recommendations.)

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

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i. positive airflow when a device is implanted, there is a skin incision, or prolonged procedure more than two hours;

ii. high flow oxygen and vacuum for suctioning;

iii. medical gas availability:

- 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 33 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

iii. equipment/supply storage areas.

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(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 bleeding complications from the extraction of chronic device leads and complex mapping/ablation procedures, particularly those requiring sawpericardial access;

i. For all other procedures, a facility must have a protocol in place for transferring the patient(s) to a tertiary facility.

Comment: Ablation and device procedures on pediatric patients, as well as patients of any age with complex congenital heart defects, should only be performed at centers with experienced cardiac surgical staff and the proper equipment to provide back-up for emergencies.[10]

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 are not limited to the following:

(See Guidelines on Page 33 for further recommendations.)

2.2.3.1A Special Procedure Rooms: Special procedures, such as, cardioversions, tilt table studies and noninvasive programmed stimulation defibrillation threshold testing require the following, but are not limited to:

i. defibrillator;
ii. procedure tables that have the capability for 70-degree head-up tilt;
iii. an electrocardiogram (ECG) monitor;
iv. non-invasive blood pressure monitor;
v. supplies specific to the procedure(s) being performed;
vi. emergency equipment and supplies as required by Standard 4.4A; and
vii. if fluoroscopy equipment is present, the equipment must comply with requirements set by these Standards (Refer to Appendix A).

2.2.3.2A Dedicated Cardiac Electrophysiology Suite: Procedures may include cardiac electrophysiology testing, ablation, device implantation, chronic lead extraction, left atrial appendage occlusion (LAAO) by device, temporary pacemakers, three-dimensional (3D) mapping, intracardiac echocardiography (ICE) and use of robotics, which must provide for/include, but are not limited to:

i. cardiac electrophysiology specific equipment:
   - electrogram recording systems;
   - three-dimensional (3D) mapping systems; and
   - programmed stimulators.
ii. defibrillator;
iii. electrocardiogram and hemodynamic monitoring equipment capabilities as described in Standard 2.3.2A;
iv. non-invasive blood pressure monitor;
v. supplies specific to the procedure(s) being performed;
vi. emergency equipment and supplies as required by Standard 4.4A;
vii. if procedure requires fluoroscopy, radiation shielded barriers that meet state and federal requirements; and
viii. if fluoroscopy equipment is present, the equipment must comply with requirements set by the Standards (Refer to Appendix A).

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(See Guidelines on Page 33 for further recommendations.)

2.2.3.3A Combined Hybrid Laboratories/Hybrid Surgical Suites: These are operating surgical rooms offering advanced mapping, ablation, device implantation capabilities and extraction of chronically implanted pacemaker or ICD leads and left atrial appendage occlusion (LAAO) by device which must provide for/include, but are not limited to:

i. cardiac electrophysiology specific equipment:
   - electrogram recording systems;
   - three-dimensional (3D) mapping systems; and
   - programmed stimulators.

ii. defibrillator;

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

iv. non-invasive blood pressure monitor;

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

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

vii. if procedure requires fluoroscopy, radiation shielded barriers that meet state and federal requirements;

viii. devices and tools used for chronic lead extraction; and

ix. if fluoroscopy equipment is present, the equipment must comply with requirements set by Standards (Refer to Appendix A).

2.2.3.4A Pediatric EP Laboratory: Procedure rooms performing pediatric cardiac electrophysiology procedures have similar requirements as that of rooms performing adult/non-congenital procedures (refer to Standard 2.2.3.2A) with the exception of the following requirements, which must include, but are not limited to:

i. pediatric resuscitation equipment;

ii. pediatric appropriate medication dosages;

iii. inventory of pediatric catheters;

iv. inventory of pediatric basic supplies: and

v. if fluoroscopy equipment is present, the equipment must comply with requirements set by the Standards (Refer to Appendix A).

2.2.3.5A Lead Extraction Procedure Room: Procedures that require the removal of a lead that has been implanted for more than one year, or a lead regardless of duration of implant requiring the assistance of specialized equipment that is not included as part of the typical implant package, and/or removal of a lead from a route other than via the implant vein. Implantable Cardioverter Defibrillator (ICD) leads may require specialized extraction equipment even when implantation duration is less than one year. Procedures can be performed in either operating rooms, or procedural laboratories specifically designed for device implantation procedures. The room must be of adequate size to allow for emergent interventions, within 10 minutes, such as thoracotomy and sternotomy.[10] The room must be equipped with a ventilation system designed to prevent surgical infections and to handle anesthetic gases. These procedures rooms must have or meet, but are not limited to:

i. emergency equipment and supplies as required Standard 4.4A;

ii. surgical instruments;
   - appropriate for transvenous lead extraction and device implantation; and

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- to perform vascular repairs, thoracotomy, sternotomy and cardio-pulmonary by-pass.

iii. extraction tools:
- simple traction using tools typically supplied for lead implant;
- traction devices;
- mechanical sheaths;
- laser sheaths;
- electrosurgical sheaths;
- rotating threaded tip sheath;
- telescoping sheaths;
- locking stylets; and
- suture materials and/or ties.

iv. extraction snares:
- large sheaths with a hemostatic valve;
- grasping device(s); and
- snaring devices.

v. Cardiovascular Implantable Electronic Device (CIED) implantation tools:
- stylets;
- wrenches;
- fixation tools;
- repair kits;
- adapters, sterile sleeves for the programmer;
- pin plugs;
- lead anchoring sleeves; and
- lead end caps.

vi. standard implantation equipment to included, but not limited to:
- introducer sheaths;
- guide wires; and
- venous entry needles.

vii. transthoracic and transesophageal echocardiography must be immediately available;

viii. anesthesia cart;

ix. invasive and non-invasive arterial pressure monitoring;

x. oxygen saturation and CO2 monitoring;

xi. pericardiocentesis tray;

xii. water seal/vacuum containers for chest tube drainage;

xiii. temporary transvenous pacemakers and connectors;

xiv. transcutaneous temporary pacing;

xv. defibrillation equipment, intravenous contrast agents;

xvi. fluids, pressors and other emergency medications;

xvii. equipment for cardio-pulmonary bypass must be readily available;

xviii. open chest tray including sternal saw and surgical instruments for open chest; and

xix. high-quality fluoroscopy equipment is present; the equipment must comply with requirements set by the Standards (Refer to Appendix A).

Comment: Lead extraction procedures must only be performed at centers with on-site cardiac surgery and cardiac catheterization programs. A cardiothoracic

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surgeon must be physically on site and capable of initiating an emergent procedure promptly. Facilities offering lead extraction and personnel participating in these programs must have a protocol for emergency response when the need arises.

Comment: Facilities offering lead extraction 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 33 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.

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

(See Guidelines on Page 33 for further recommendations.)

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.

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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.

STANDARD – Device Clinic

2.5A The following procedure room type/area must comply with Standards 2.1A through 2.2A above and meet, but are not limited to, the following requirements:

2.5.1A Device clinic procedure room(s) must meet, but are not limited to, the following requirements:

2.5.1.1A 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.

2.5.1.2A General Room Lighting: Overhead and task lighting must be adequate to perform device management, cardiac rhythm analysis, remote monitoring and for clinical evaluation of the patient.

2.5.1.3A Room Power: The facility must have a plan that outlines the response to unexpected power loss or computer function, such as movement of the patient to another similarly capable room in the immediate vicinity.

i. Utilization of emergency power must be visible by the operator at the normal working position.

ii. An uninterruptible power supply for all computer equipment is recommended.

2.5.1.4A Emergency equipment and supplies to include:

i. oxygen/suction;
ii. biphasic external defibrillator with a backup defibrillator immediately accessible;
iii. standard Advance Cardiac Life Support (ACLS) medications (including a master list facility required medications with verification of expiration date);
iv. resuscitator bag and mask;
v. non-rebreather mask; and
vi. other facility required equipment and supplies.

2.6A Quality Control Documentation

2.6.1A All equipment preventative maintenance, service and quality control results must be documented and reviewed. The reports must be signed and dated by the person(s) performing the tests.

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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 EP laboratories with a goal to improve work flow in the EP environment.

The minimal procedural area of a complete EP 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.

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.

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

Advanced mapping systems should be available for complex ablation procedures.

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

2.2.2.5i For procedure areas where CIEDs are implanted; airflow should meet or exceed the published CDC Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines.[21]

2.2.2.7A Electronic storage of cardiac electrophysiology 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.

2.2.3A 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.

2.3.3.2A An additional 45 inches of desk space is suggested for a two-monitor reading station or single-monitor workstation.

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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 cardiac electrophysiology procedure and device clinic overview described below is not intended to be a comprehensive list of requirements to perform a case or post-procedural onsite and longitudinal remote monitoring of implantable devices, 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.

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

Comment: 1.1.1B through 1.9.3.6B is not applicable for device clinic accreditation (See Standards 1.10B through 1.14B).

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

(See Guidelines on Pages 67-72 for further recommendations.)

1.1.3B All staff must observe adherence to:

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

1.1.3.2B national patient safety goals as it applies to medication safety;

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

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

(See Guidelines on Pages 67-72 for further recommendations.)

STANDARD – Procedure Requirements

1.2B Prior to performance of the procedure:

1.2.1B An adequate supply of devices approved by the FDA for marketing or investigational use must be available. This includes, but is not limited to: diagnostic catheters, therapeutic catheters and implantable devices.

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

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The facility must have policy in place for the oversight of distribution for pharmacologic agents by a clinical pharmacist.

1.2.3B Proper identification of the patient and planned procedure must be carried out prior to puncture according to national patient safety goals and the proper patient name or identification (ID) must be present on the imaging system.[13] This must be performed immediately before the initiation of the procedure when all key personnel are present.

1.2.4B All procedures, performed with or without moderate sedation and/or with or without general anesthesia, must be explained to the patient and/or the parents or guardians of those unable to give informed consent. Consent must be obtained in a manner consistent with the rules and regulations required by the hospital or facility. During the use of moderate sedation and/or general anesthesia there must be methods in place to assess the patient's level of consciousness pre-procedure and throughout the procedure. Written policies must exist for the use of conscious sedation including, but not limited to:

1.2.4.1B type of sedatives and appropriate dosing; and

1.2.4.2B monitoring during and after the examination.

(See Guidelines on Pages 67-72 for further recommendations.)

1.2.5B A fire safety evaluation must be performed prior to the start of the procedure.[14,15,16] This must be performed immediately before the initiation of the procedure when all key personnel are present.

1.2.6B History and physical examination must be performed within 30 days and should be in the chart and include documentation of relevant laboratory testing, medications, allergies and bleeding disorders.

1.2.7B Document pre-procedural rhythm either in the form of a 12-lead ECG or rhythm strip.

1.2.7.1B For device implantation procedures; within one month prior to procedure.

1.2.7.2B For testing and ablation procedures; immediately prior to procedure.

1.2.8B Cardiovascular assessment, must be documented.

1.2.8.1B Patients undergoing a cardiac electrophysiology procedure will undergo cardiovascular assessment prior to and following the procedure to document pre-procedural status, post-procedural status and evaluate for any procedural complications. Cardiovascular assessment must include, but not limited to:

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

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

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1.2.9B 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.

1.2.9.1B In the case of chronic lead extraction, four units (typed and cross-matched) should be available.

1.2.10B When applicable, antithrombotic therapy should be administered prior to the procedure, during the procedure and after the procedure.

1.2.11B Self-adhesive external defibrillation pads must be place on the patient's chest prior to the onset of the procedure.

1.2.12B The facility must have a process to address procedural complications (Refer to Standard 3.1.2C).

1.2.13B For any surgical incisions, to include but not limited to: device implantation, chronic lead extraction and generator change. Administration of an antibiotic, usually a first-generation cephalosporin, within one hour before implantation is required.

1.2.14B For patients with CIED-related infections, a plan for pre-, intra- and post-operative antibiotics must be formulated, including the type, route and duration of antibiotics. The need for additional testing, such as transesophageal echocardiography to evaluate for the presence and/or size of vegetations, must be determined as this will help determine the most appropriate approach (transvenous or open surgical) for the extraction.

1.2.15B The operator must be aware of all device and lead hardware present, including those in use and previously abandoned.

1.2.16B For chronic lead extraction, procedure preparation must also include:

1.2.16.1B large bore (18 gauge or larger) venous access;

1.2.16.2B continuous electrocardiographic monitoring;

1.2.16.3B blood pressure monitoring (invasive or non-invasive); and

1.2.16.4B skin prep to allow for emergent pericardiocentesis, thoracotomy, sternotomy and cardio-pulmonary bypass.

1.2.17B For left atrial appendage occlusion (LAAO) by device, procedure preparation must also include:

1.2.17.1B continuous electrocardiographic monitoring;

1.2.17.2B blood pressure monitoring (invasive or non-invasive); and

Comment: Recommendations for LAAO by device apply only to those patients in whom the benefits of LAAO by device outweigh the risks when assessed based on individualized patient factors and operator-specific experience and outcomes.

(See Guidelines on Pages 67-72 for further recommendations.)

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1.3B During the performance of the procedure:

1.3.1B Cardiac pacing supplies and all necessary equipment, according to Standard 2.4A must be available.

1.3.2B Standard Advance Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) medications must be available, according to Standard 2.4.2.5A.

1.3.3B Physiologic monitoring must include continuous electrocardiographic monitoring:

1.3.3.1B blood pressure monitoring (invasive or non-invasive);

1.3.3.2B pulse oximetry; and

1.3.3.3B capnography may be used (if appropriate).

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

1.3.5B Radiation must be monitored during the procedure.

1.3.5.1B Radiation use must be consistent with the "as low as reasonably achievable" principle or ALARA radiation safety guidelines.

1.3.6B Adequate anticoagulation should be monitored with activated clotting time (ACT) throughout the procedure.

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.[23,29,31,34,35]

1.4.3.1B Complications may include, but not limited to:

i. acute renal failure;
ii. cardiac arrest;
iii. cardiac perforation;
iv. cardiac valve injury;
v. conduction block;
vi. coronary venous dissection;
vii. hematoma;
viii. hemothorax;

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ix. lead dislodgement;
x. 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.

xi. pericardial effusion;
xii. peripheral embolus;
xiii. pneumothorax;
xiv. transient ischemic attach (TIA) or stroke; and
xv. other.

(See Guidelines on Pages 67-72 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. 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 EP patients.

1.4.5B Document post-procedural rhythm either in the form of a 12-lead ECG or rhythm strip.

1.4.6B Document post-procedure cardiovascular assessment within approximately 24 hours and/or prior to discharge.

(See Guidelines on Pages 67-72 for further recommendations.)

1.4.7B Document discharge instructions for patient and/or family.

1.4.8B 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[17] (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 preliminary and final reports.

1.5.3B Routine inpatient cardiac electrophysiology 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.

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1.6B Cardiac electrophysiology 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 cardiac electrophysiology 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. anesthesia risk assessment;
v. baseline heart rate, baseline blood pressure prior to the start of the procedure; and
vi. allergies.

1.6.1.3B Procedural data, when applicable:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;
v. activated clotting time(s) (ACT), if applicable;
vi. arterial blood gas, if applicable;
vii. medications administered;
- dose; and
- time given.

viii. vascular access;
- sites;
- sheath size; and
- sheath-in time.

ix. induced arrhythmias;

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x. cardioversions;
xi. sheath removal;
xii. fluoroscopic exposure, when applicable, list:
- fluoroscopy time and one or more of the following:
  - radiation dose; and
  - dose-area product.

xiii. contrast agent(s), if used, the following must be documented:
- name of contrast(s);
- volume(s) injected; and
- other data, as required.

xiv. additional imaging, when applicable:
- intracardiac echocardiography (ICE);
- transthoracic echocardiography;
- transesophageal echocardiography; and
- other imaging, as required.

xv. other data/information, as required.

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 Preprocedural data:

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

1.6.2.2B 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.

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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 cardiac electrophysiology 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:

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;
ii. catheter placement;
iii. transseptal access technique; and
iv. pericardial access technique.

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

i. baseline intervals;
ii. atrial function;
iii. atrioventricular nodal function;
iv. His-Purkinje function;
v. ventricular function; and
vi. accessory pathway function.

1.6.3.4B A summary of the results of induced arrhythmias including (when applicable);

i. rate;
ii. morphology;
iii. response to pacing maneuvers;
iv. response to pharmacological maneuvers;
v. tachycardia mechanism;
vi. method of induction; and
vii. duration (sustained vs spontaneously terminating).

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1.6.3.5B A summary of the results of arrhythmia mapping including (when applicable);

i. mapping system employed;
ii. activation mapping;
iii. entrainment mapping;
iv. pace mapping; and
v. navigation system.

1.6.3.6B A summary of electrical cardioversion including (when applicable):

i. baseline arrhythmia;
ii. additional imaging results (if applicable);
iii. method of defibrillation delivery:
    - paddles; or
    - self-adhesive external defibrillation pads.
iv. defibrillation attempt(s);
v. amount of energy delivered; and
vi. post-procedural rhythm.

1.6.3.7B A summary of the results of catheter ablation including (when applicable);

i. baseline arrhythmia;
ii. insertion site(s) and all catheters inserted;
iii. arrhythmia mechanism;
iv. maneuvers to identify arrhythmia mechanism;
v. anatomical location of arrhythmia origin;
vi. targeted sites(s);
vii. description of transseptal procedure, if performed;
viii. ablation catheters and technology employed for the following mode(s):
    - radiofrequency (RF);
    - irrigated RF;
    - ultrasound;
    - microwave;
    - laser;
    - cryothermal; and
    - other.
ix. navigation system;
x. post-ablation rhythm;
xi. acute outcome; and
xii. acute complications.[23,29,30,31,34,35]

(See Guidelines on Pages 67-72 for further recommendations.)

1.6.3.8B 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.

1.6.3.9B A summary/conclusion of the results of the procedure, including any positive and

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negative findings or adverse outcomes.

1.6.3.10B If appropriate, need for additional studies and/or procedures based on the results of the procedure being reported.
Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This conclusion must resolve the clinical question or provide guidance for further studies to do so.

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

1.7B Cardiac implantable electrophysiology device (CIED) implant 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, including:

1.7.1.1B Demographics:

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

1.7.1.2B Baseline data:

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

(See Guidelines on Pages 67-72 for further recommendations.)

1.7.1.3B Procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;

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v. medications administered;
- dose; and
- time given.

vi. vascular access;
- sites;
- sheath size; and
- sheath-in time.

vii. lead placement;

viii. device placement;

ix. induced arrhythmias;

x. cardioversions;

xi. fluoroscopic exposure, when applicable, list:
- fluoroscopy time and one or more of the following:
  - radiation dose; and
  - dose-area product.

xii. contrast agent(s), if used, the following must be documented.
- name of contrast(s);
- volume(s) injected; and
- other data, as required.

xiii. additional imaging, when applicable:
- intracardiac echocardiography (ICE);
- transthoracic echocardiography;
- transesophageal echocardiography;
- other imaging, as required; and
- other data/information, as required.

1.7.1.4B Device documentation must include, but not limited to:

i. pulse generator manufacturer; model and serial number;
- Universal Device Identifier (UDI), when available;

ii. pacing lead(s);

iii. lead model and serial numbers;

iv. Universal Device Identifier(s) (UDI), when available; and

v. acute and chronic lead parameters (see Appendix B).

Comment: Sidedness must be indicated for all lead positions and measurement sample sites for testing when referring to data described in this section (Anatomical description(s) for lead position and measurement sample sites may be used in cases of complex congenital heart disease.).

1.7.1.5B Post-procedural data:

i. blood pressure;

ii. heart rate;

iii. rhythm;

iv. level of consciousness;

v. oxygenation; and

vi. hemostasis.

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

1.7.2.1B Pre-procedural data:

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

1.7.2.2B Procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. medications administered;
v. level of anesthesia/sedation;
vi. oxygenation; and
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; and
v. oxygenation.

1.7.3B Physicians reporting CIED implant procedures must accurately describe the key aspects of the procedure. The report must include but may not be limited to:

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 procedure; 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. incision site(s);
ii. vascular access site(s);
iii. additional introducer guide catheters or sheaths employed;

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iv. description of angiographic findings;
v. lead position(s);
vi. pocket location; and
vii. wound closure.

1.7.3.3B A summary of the results of lead testing including (when applicable, if not reported elsewhere):

i. P/R wave amplitude;
ii. pacing threshold(s) in pertinent lead configurations;
iii. lead impedance(s); and
iv. defibrillation threshold.

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 Any need for additional studies and/or procedures based on the results of the procedure being reported.

Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This conclusion must resolve the clinical question or provide guidance for further studies to do so.
Comment: A record of pre-procedural and post-procedural physiologic measures and laboratory data must be maintained and immediately available when referencing the final report.

1.7.3.7B Any need for additional studies and/or procedures based on the results of the procedure being reported.

1.8B Cardiac electrophysiology chronic lead extraction 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.

1.8.1B The nursing or technical record must include all technical aspects of the procedure as listed in Standard 1.6.1.1B, unless recorded in the anesthesia record including:

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 cardiac electrophysiology procedure; and

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

1.8.1.2B Baseline data:

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

(See Guidelines on Pages 67-72 for further recommendations.)

1.8.1.3B Procedural data, when applicable:

i. blood pressure measurement(s) to include invasive blood pressure monitoring (e.g., arterial line);
ii. heart rate;
iii. rhythm;
iv. systemic oxygen saturation and/or pO2;
v. activated clotting time(s) (ACT), if applicable;
vi. arterial blood gas, if applicable;
vii. medications administered;
- dose; and
- time given.

viii. vascular access;
- sites;
- sheath size; and
- sheath-in time.

ix. induced arrhythmias;
x. cardioversions;
xi. sheath removal;
xii. fluoroscopic exposure, when applicable, list:
- fluoroscopy time and one or more of the following:
  - radiation dose; and
  - dose-area product.

xiii. contrast agent(s), if used, the following must be documented:
- name of contrast(s);
- volume(s) injected; and
- other data, as required.

xiv. additional imaging, when applicable:
- intracardiac echocardiography (ICE);
- transthoracic echocardiography;
- transesophageal echocardiography; and
- other imaging, as required.

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xv. other data/information, as required.

1.8.1.4B Device, lead and adapter information (connected and abandoned) must include, but not limited to:

i. pulse generator manufacturer; model and serial number;
- Universal Device Identifier (UDI), when available.

ii. pacing lead(s):
- lead model and serial numbers

iii. Universal Device Identifier(s) (UDI), when available:
- access route;
- insertion site(s)/lead placement(s);
- other, as required.

iv. location and description of abandoned device, lead(s) and adapter(s);

v. disposition of explanted material (e.g., pathology, bacteriology, industry, etc.);

vi. time to individual lead removal/extraction; and

vii. other data, as required.

Comment: Sidedness must be indicated for all lead positions and measurement sample sites for testing when referring to data described in this section (Anatomical description(s) for lead position and measurement sample sites may be used in cases of complex congenital heart disease.).

1.8.1.5B Post-procedural data:

i. blood pressure;

ii. heart rate;

iii. rhythm;

iv. level of consciousness;

v. oxygenation; and

vi. 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; and

vi. allergies.

1.8.2.2B Procedural data:

i. blood pressure measurement(s) to include invasive blood pressure monitoring (e.g., arterial line);

ii. heart rate;

iii. rhythm;

iv. medications administered;

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

1.8.2.3B Post-procedural data:

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

1.8.3B Physicians reporting chronic lead extraction procedures must accurately describe the key aspects of the procedure. The report must include but may not be limited to:

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

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

i. incision site(s);
ii. vascular access site(s);
iii. additional introducer guide catheters or sheaths employed;
iv. description of angiographic findings;
v. lead position(s);
vi. pocket location;
vii. successful/partial or failed explant;
viii. in the presence of infection, description of pocket findings and documentation of cultures taken; and
ix. wound closure.

1.8.3.3B A summary of the results of lead testing including (when applicable, if not reported elsewhere):

i. P/R wave amplitude;
ii. pacing threshold(s) in pertinent lead configurations;
iii. lead impedance(s); and
iv. defibrillation threshold.

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

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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 Any need for additional studies and/or procedures based on the results of the procedure being reported.

Comment: An accurate, succinct impression (e.g., normal, abnormal, stable). This must clearly communicate the result(s) of the procedure. This conclusion must resolve the clinical question or provide guidance for further studies to do so.
Comment: A record of pre-procedural and post-procedural physiologic measures and laboratory data must be maintained and immediately available when referencing the final report.

1.8.3.7B Any need for additional studies and/or procedures based on the results of the procedure being reported.

1.9B Left atrial appendage occlusion (LAAO) by device 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 A for examples qualifying LAAO by device procedure types.

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

1.9.1.1B Demographics:

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

1.9.1.2B Baseline data:

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.

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(See Guidelines on Pages 67-72 for further recommendations.)

1.9.1.3B Procedural data, when applicable:

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

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

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

xv. angiography:
- type of contrast(s);
- for each angiogram:
  - time of injection;
  - site;
  - dose (ml);
  - 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:
- intervention type(s) (closure, ligation or clipping);
- intervention data;
  - plasty, when applicable:
    1. balloon diameter, length and type;

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2. number of inflation(s);
3. pounds per square inch (PSI) and duration of inflation(s);
4. other.

- device used (new and abandoned), when applicable:
  1. number of device(s);
  2. site of placement(s);
  3. manufacturer(s);
  4. device identification information:
     - manufacturer;
     - model;
     - serial number; and
     - size(s).
  5. other.
- other.

xviii. other data/information, as required.

- Documentation of device specific successful implant criteria.
  - (Compression, position, leaks, stability)

1.9.1.4B Post-procedural data:

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

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

1.9.2.1B Pre-procedural data:

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

1.9.2.2B Procedural data:

i. blood pressure;
ii. heart rate;
iii. rhythm;
iv. medications administered;
v. level of anesthesia/sedation;
vi. oxygenation;
vii. capnography measures, if applicable;

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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 left atrial appendage occlusion (LAAO) by device 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. epicardial access description (when applicable);
iii. catheter used and placement;
iv. transseptal access technique;
v. imaging modalities used:
vi. detailed description of the procedure; and
vii. other.

1.9.3.3B A summary of left atrial appendage occlusion (LAAO) by device including (when applicable):

i. description of LAA anatomy;
ii. detailed report of hemodynamics and oximetry data;
iii. device(s) used (new):
- number of devices used;
- manufacturer;
- model;
- size; and
- type.
iv. documentation of device specific successful implant criteria;
v. recommendation for ongoing management;

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vi. procedural complication(s); and

vii. 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.

STANDARD – Monitoring, Evaluation and/or Programming Requirements (Device Clinic Only)

1.10B Prior to performance of monitoring, evaluation and/or programming (device clinic only):

1.10.1B An adequate supply of manufacturer approved device interrogation equipment. This includes, but is not limited to: interrogation, interpretation and reporting devices for Cardiac Implantable Electronic Devices (CIED).

1.10.2B Proper identification of the patient and evaluation and monitoring plan must be carried out prior to monitoring and evaluation according to national patient safety goals and the proper patient name or identification (ID) must be present on the monitoring and evaluation equipment.[13]

1.10.3B History and physical examination must be performed prior to the initial device Clinic visit and should be in the chart and include documentation of relevant laboratory testing, medications, allergies and bleeding disorders.

1.10.4B Document pre-monitoring or evaluation rhythm.

1.10.5B When applicable, laboratory testing should be ordered and documented.

1.10.6B Document presence of abandoned device and lead hardware.

1.10.7B Establish process for the management of manufacture and/or FDA advisories/recalls.

1.10.8B Document written patient consent to be followed in the device clinic.

1.11B During the performance of monitoring, evaluation and/or programming (in-person device clinic only):

1.11.1B All necessary interrogation, interpretation and reporting equipment for Cardiac Implantable Electronic Devices (CIED), must be available.

1.11.2B CIED information must be entered into a secured database/Electronic Medical Record (EMR), which must include:

1.11.2.1B query functionality (be searchable); and

1.11.2.2B have the ability to flag manufacturer and/or FDA advisories/recalls.

1.11.3B Document device site:

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1.11.3.1B appearance; and

1.11.3.2B location.

1.11.4B Documentation of CIED information to include, but not limited to:

1.11.4.1B mode(s);

1.11.4.2B Universal Device Identifiers (UDI);

1.11.4.3B pulse generator manufacturer;

1.11.4.4B model and serial number; and

1.11.4.5B lead model and serial numbers.

1.11.5B Document the type of enrollment to include, but not limited to:

1.11.5.1B new enrollment;

1.11.5.2B transfers of care/referrals; and

1.11.5.3B other.

1.11.6B Document CIED evaluative protocol types to include, but not limited to:

1.11.6.1B interrogation only; or

1.11.6.2B full or partial programming to include one or more of the following:

i. sensing threshold;
ii. stimulation threshold; and/or
iii. underlying rhythm.

1.11.6.3B data stored/saved to an Electronic Medical Records (EMR) system to include, but not limited to:

i. collected programmer data/summaries;
ii. initial summary;
iii. diagnostic data;
iv. final programmed parameters;
v. changes in programmed parameters;
vi. collected rhythm strips;
vii. presenting rhythm;
viii. underlying rhythm (and/or sensing thresholds);
ix. stimulation thresholds (at least one of each lead); and
x. final rhythm strip (if reprogramming was performed resulting in a change in the rhythm).

1.11.7B Document evaluation reporting elements to include but not limited to:[37]

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1.11.7.1B type of evaluation:

i. unscheduled vs. scheduled;
ii. interrogation only;
iii. thresholds; and
iv. programming for a specific issue.

1.11.7.2B presenting rhythm:

1.11.7.3B summary of testing, if performed;

1.11.7.4B arrhythmia findings summary:

i. atrial; or
ii. ventricular.

1.11.7.5B heart failure data, when applicable;

1.11.7.6B device projected battery longevity or battery voltage;

1.11.7.7B plan of care; and

1.11.7.8B other.

1.11.8B Triage applicable evaluation findings to include, but not limited to:

1.11.8.1B CIED functioning abnormalities, when applicable;

1.11.8.2B stimulation abnormalities, when applicable;

1.11.8.3B rhythms/conduction abnormalities of concern, when applicable;

1.11.8.4B battery depletion, when applicable;

1.11.8.5B Emergency Medical Services (EMS) vs. patient sent to the emergency room, when applicable; and

1.11.8.6B request for professional interpretation and signature, when applicable.

1.11.9B Documentation of EMR storage.

1.12B Remote CIED performance of monitoring, evaluation and/or programming (device clinic only):

1.12.1B Remote CIED evaluation and reporting must include all elements listed in Standards 1.10.6B through 1.14.8B.

1.12.2B Remote CIED program must include:

1.12.2.1B documentation of remote website administrator(s) for management of:

i. users;
ii. usernames; and
iii. passwords.

1.12.3B Process in which each CIED manufacturer's website data is:

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1.12.3.1B reviewed;

1.12.3.2B entered into the device clinic database; and

1.12.3.3B dismissed or archived within the manufacturer's website.

1.12.4B Document device site photos transmitted by patient.

1.13B Following the performance of monitoring, evaluation and/or programming (device clinic only):

1.13.1B Reporting CIED implant procedures must accurately describe the key aspects of the monitoring, evaluation and/or programming.

1.13.2B 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. The report must include but may not be limited to:

1.13.2.1B A summary/conclusion of the results of the procedure, including any positive and negative findings or adverse outcomes.

1.13.3B Process of notifying the patient and referring physician of the results must occur in a timely fashion.

1.13.4B Document frequency of follow-up:

1.13.4.1B Post implant:

i. completely new device (system);
ii. generator only with chronic leads; and
iii. leads only.

1.13.4.2B Post procedure:

i. electrophysiology testing study (EPS);
ii. ablation;
iii. DC cardioversion (DCCV); and
iv. coronary artery bypass graft (CABG).

1.13.5B If needed, document reason for discontinuing follow-up to include, but not limited to:

1.13.5.1B lost to follow-up;

1.13.5.2B transfer to another service provider/device clinic;

1.13.5.3B hospice; and

1.13.5.4B death.

1.13.6B Device clinic 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.

1.14B Program must provide parameters for peri-procedure device management to include, but not limited to:

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1.14.1B magnetic resonance imaging (MRI);

1.14.2B surgeries;

1.14.3B spinal radio frequency (RF) ablations;

1.14.4B stress echocardiography;

1.14.5B computed tomography angiography (CTA); and

1.14.6B other.

Comment: When appropriate, an ACLS- or PALS-certified staff member must be present for all device program changes prior to and post peri-procedures listed above.

STANDARD – Procedure Volumes

1.15B The procedure volume must be sufficient to maintain proficiency in procedure performance and interpretation.

1.15.1B The facility must have specific privileging requirements for individual operators to perform invasive cardiac electrophysiology procedures to include, but not limited to: cardiac electrophysiology testing and ablation, device implantation, chronic lead extraction and left atrial appendage occlusion (LAAO) by device.

(See Guidelines on Pages 67-72 for further recommendations.)

Section 1B: Procedures and Protocols *Guidelines*

1.1B *In most diagnostic and ablation cases, rhythm active drugs (including β-blockers and calcium-channel blockers) are discontinued five half-lives before the procedure to allow the target arrhythmia to be induced, mapped, and ablated.*

All physicians and staff are required to be familiar with identifying all potential procedural complications and to 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 EP 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 reflecting expertise in the management and treatment of cardiac arrhythmias.*
- *It is desirable that anesthesia services be an integral part of clinical practice in the EP 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 EP laboratory.*
- *Industry representatives should function according to clear policies under the direction of the laboratory manager, staff, or physician.*
- *Additional laboratory staff should include, but is not limited to, registered nurses (RNs), EP specialists/technologists, radiological technologists, and certified nurse practitioners (NPs) and Physician Assistants (PAs) as needed.*

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- *Additional appropriately trained personnel should be provided to staff patient prep, recover and OR areas.*
- *Other key personnel that are important for the safe and efficient function of the laboratory include quality improvement (QI) staff, information technologists, biomedical engineers, scheduling coordinators, purchasing, inventory and supply personnel, and housekeeping.*

1.2B In patients undergoing pacemaker or defibrillator lead extraction, or who require pericardial access for epicardial ablation or left atrial ablation ligation, 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.

1.2.4B A complete description of the procedure, including the anticipated success rates and possible complications, is best delivered in the outpatient setting before the EP procedure.

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

1.4.6B 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.

1.4.3.1B and 1.6.3.7B Complication definitions include, but not limited to: [23-92,30,31]

EP Studies and Ablation

Major Complication: A major complication is a complication that results in permanent injury or death, requires intervention for treatment, or prolongs or requires hospitalization for more than 48 hours. (Excluding early recurrent AF/AFL/AT within three months that requires or prolongs a patient's hospitalization).

Serious Adverse Device Effect: A serious adverse device effect is defined as a serious adverse event that is attributed to use of a particular device.[23,29,31,34,35]

- *Acute Renal Failure*
- *Atrio Esophageal Fistula*
- *Bleeding*
- *Bleeding Following Cardiac Surgery*
- *Cardiac Tamponade/Perforation*
- *CHF exacerbation with increased length of stay*
- *Conduction abnormalities*
- *Death*
- *Deep Sternal Wound Infection/Mediastinitis following Cardiac Surgery*
- *Drug reaction—anaphylaxis (specify drug implicated as cause of reaction)*
- *Esophageal Injury*
- *Gastric Motility/Pyloric Spasm Disorders*
- *Hemothorax*
- *Mediastinitis*
- *Myocardial Infarction*
- *Pericarditis*
- *Phrenic Nerve Paralysis*
- *Pneumothorax*
- *Pulmonary Vein Stenosis*
- *Pulmonary embolism*
- *Sepsis, abscesses, or endocarditis*
- *Silent Cerebral Embolism*
- *Stroke or TIA Post Ablation*
- *Unanticipated Adverse Device Effect*
- *Valve damage/requiring surgery*
- *Vagal Nerve Injury*
- *Vascular Access Complication*

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- *Vascular dissection/occlusion (Including DVT)*

Atrio Esophageal Fistula: An atrio esophageal fistula is defined as a connection between the atrium and the lumen of the esophagus. Evidence supporting this diagnosis includes documentation of esophageal erosion combined with evidence of a fistulous connection to the atrium such as air emboli, an embolic event, or direct observation at the time of surgical repair. A CT scan or MRI scan are the most common methods of documentation of an atrial esophageal fistula.

Bleeding: Bleeding is defined as a major complication of AF ablation if it requires and/or is treated with transfusion or results in a 20% or greater fall in HCT.

Bleeding Following Cardiac Surgery: Excessive bleeding following a surgical AF ablation procedure is defined as bleeding requiring reoperation or >2 units of PRBC transfusion within any 24 hours of the first 7 days following the index procedure.

Cardiac Tamponade/Perforation: Cardiac tamponade/perforation is defined as the development of a significant pericardial effusion during or within 30 days of undergoing an AF ablation procedure. A significant pericardial effusion is one that results in hemodynamic compromise, requires elective or urgent pericardiocentesis, or results in a 1-cm or more pericardial effusion as documented by echocardiography. Cardiac tamponade/perforation should also be classified as "early" or "late" depending on whether it is diagnosed during or following initial discharge from the hospital.

Deep Sternal Wound Infection/Mediastinitis following Cardiac Surgery:

This requires one of the following:

1. *an organism isolated from culture of mediastinal tissue or fluid;*
2. *evidence of mediastinitis seen during operation;*
3. *one of the following conditions: chest pain, sternal instability, or fever (>38 °C), in combination with either purulent discharge from the mediastinum or an organism isolated from blood culture or culture of mediastinal drainage.*

Esophageal Injury: Esophageal injury is defined as an erosion, ulceration, or perforation of the esophagus. The method of screening for esophageal injury should be specified. Esophageal injury can be a mild complication (erosion or ulceration) or a major complication (perforation).

Gastric Motility/Pyloric Spasm Disorders: Gastric motility/pyloric spasm disorder should be considered a major complication of AF ablation when it prolongs or requires hospitalization, requires intervention, or results in late disability, such as weight loss, early satiety, diarrhea, or GI disturbance.

Mediastinitis:

Diagnosis of Mediastinitis requires one of the following:

1. *an organism isolated from culture of mediastinal tissue or fluid;*
2. *evidence of mediastinitis seen during operation;*
3. *one of the following conditions: chest pain, sternal instability, or fever (>38 °C), in combination with either purulent discharge from the mediastinum or an organism isolated from blood culture or culture of mediastinal drainage.*

Myocardial Infarction in the Context of AF Ablation: The universal definition of myocardial infarction[28] including chest pain and rise in cardiac biomarkers (troponin and CPK) cannot be applied in the context of catheter or surgical AF ablation procedures. It is proposed that an MI in that context be defined as the presence of any one of the following criteria:

1. *detection of ECG changes indicative of new ischemia (new ST-T changes or new LBBB), which persist for more than one hour;*
2. *development of new pathological Q waves on an ECG;*
3. *imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.*

Pericarditis: Pericarditis should be considered a major complication following ablation if it results in an effusion that leads to hemodynamic compromise or requires pericardiocentesis, prolongs hospitalization by more than 48 hours, requires hospitalization, or persists for more than 30 days following the ablation procedure.

Phrenic Nerve Paralysis: Phrenic nerve paralysis is defined as absent phrenic nerve function as assessed by a sniff test. A phrenic nerve paralysis is considered to be permanent when it is documented to be present 12 months or longer following ablation.

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Pulmonary Vein Stenosis: Pulmonary vein stenosis is defined as a reduction of the diameter of a PV or PV branch. PV stenosis can be categorized as mild <50%, moderate 50%-70%, and severe >70% reduction in the diameter of the PV or PV branch. A severe PV stenosis should be considered a major complication of AF ablation.

Silent Cerebral Embolism: Silent cerebral embolism is defined as an occlusion of a blood vessel in the brain due to an embolus that does not result in any acute clinical symptoms. Silent cerebral embolism is generally detected using a diffusion-weighted MRI.

Stroke or TIA Post Ablation:

Stroke Diagnostic Criteria:

- *Rapid onset of a focal or global neurological deficit with at least one of the following: change in level of consciousness, hemiplegia, hemiparesis, numbness or sensory loss affecting one side of the body, dysphasia or aphasia, hemianopia, amaurosis fugax, or other neurological signs or symptoms consistent with stroke.*
- *Duration of a focal or global neurological deficit >24 hours; or < 24 hours if therapeutic intervention(s) were performed (e.g., thrombolytic therapy or intracranial angioplasty); or available neuroimaging documents a new hemorrhage or infarct; or the neurological deficit results in death.*
- *No other readily identifiable nonstroke cause for the clinical presentation (e.g., brain tumor, trauma, infection, hypoglycemia, peripheral lesion, pharmacological influences)*
- *Confirmation of the diagnosis by at least one of the following: neurology or neurosurgical specialist; neuroimaging procedure (MR or CT scan or cerebral angiography); Lumbar puncture (i.e., spinal fluid analysis diagnostic of intracranial hemorrhage)*
- *Stroke definitions*
- *Transient ischemic attack: new focal neurological deficit with rapid symptom resolution (usually 1 to 2 hours), always within 24 hours; neuroimaging without tissue injury*
- *Stroke: (diagnosis as above, preferably with positive neuroimaging study);*
  - *Minor - Modified Rankin score < 2 at 30 and 90 days*
  - *Major - Modified Rankin score ≥ 2 at 30 and 90 days*

Unanticipated Adverse Device Effect: Unanticipated adverse device effect is defined as complication of an ablation procedure that has not been previously known to be associated with catheter or surgical ablation procedures.

Vagal Nerve Injury: Vagal nerve injury is defined as injury to the vagal nerve that results in esophageal dysmotility or gastroparesis. The vagal nerve injury is considered to be a major complication if it prolongs hospitalization, requires hospitalization, or results in ongoing symptoms for more than 30 days following an ablation procedure.

Vascular Access Complication: Vascular access complications include development of a hematoma, an AV fistula, or a pseudoaneurysm. A major vascular complication is defined as one that requires intervention such as surgical repair or transfusion, prolongs the hospital stay, or requires hospital admission.

Device Implantation

Major complications:

- *Death within 30 days related to the procedure*
- *Cardiac arrest within 24 hours of the procedure*
- *Respiratory arrest/failure within 24 hours of the procedure requiring ventilator support /intubation*
- *Acute coronary syndrome directly related to the procedure*
- *Cardiac perforation with or without pericardial tamponade, requiring pericardiocentesis or other surgical intervention*
- *Pneumothorax requiring observation or chest tube placement*
- *Hemothorax*
- *Stroke within 30 days of the replacement procedure*
- *Hemodynamic instability during the procedure requiring unplanned intervention and/or aborting the procedure*
- *Infection requiring intravenous antibiotics and or system removal/extraction*
- *Generator or lead malfunction requiring reoperation*

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- *Pocket revision requiring reoperation*
- *Prolonged hospitalization attributable to the device replacement procedure*
- *Hematoma requiring evacuation, drainage, blood transfusion, hospitalization, or extension of hospital stay to treat hematoma*
- *Hospital readmission directly related to the generator replacement procedure*
- *Coronary venous dissection with hemodynamic instability*
- *Pulmonary embolus*
- *Peripheral arterial embolus*
- *Deep vein thrombosis*
- *Drug reaction resulting in an aborted procedure*
- *Cardiac valve injury*
- *New AV conduction block developing as a result of the procedure*
- *AV fistula related to the replacement procedure*

Minor Complications:

- *Hematoma lasting >7 days with tenseness, drainage, or minor dehiscence managed as an outpatient*
- *Hematomas without tenseness but requiring additional outpatient evaluation*
- *Implant related pain lasting >7 days requiring prolonged use of narcotic pain medications*
- *Cellulitis treated as an outpatient with oral antibiotics*
- *Stitch abscess*
- *Unanticipated device reprogramming resulting from inadequate lead performance with significant patient symptoms or status change, excluding asymptomatic threshold changes*
- *Reversal of sedation for respiratory compromise requiring benzodiazepine or opioid receptor antagonist*
- *Peripheral nerve injury*
- *Superficial phlebitis*

Chronic Lead Extraction

Major Complication: Any of the outcomes related to the procedure which is life threatening or results in death. In addition, any unexpected event that causes persistent or significant disability, or any event that requires significant surgical intervention to prevent any of the outcomes listed.

Minor Complication: Any undesired event related to the procedure that requires medical intervention or minor procedural intervention to remedy, and does not limit persistently or significantly the patient's function, nor does it threaten life or cause death.

Major Complications:

- *Death*
- *Cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair*
- *Vascular avulsion or tear (requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair)*
- *Pulmonary embolism requiring surgical intervention*
- *Respiratory arrest or anesthesia related complication leading to prolongation of hospitalization*
- *Stroke*
- *Pacing system related infection of a previously non-infected site*

Minor Complications:

- *Pericardial effusion not requiring pericardiocentesis or surgical intervention*
- *Hemothorax not requiring a chest tube*
- *Hematoma at the surgical site requiring reoperation for drainage*
- *Arm swelling or thrombosis of implant veins resulting in medical intervention*
- *Vascular repair near the implant site or venous entry site*
- *Hemodynamically significant air embolism*
- *Migrated lead fragment without sequelae*
- *Blood transfusion related to blood loss during surgery*

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- *Pneumothorax requiring a chest tube*
- *Pulmonary embolism not requiring surgical intervention*
- *Distal embolization of lead fragment without clinical sequela*

1.7.1.2B, 1.8.1.2B, 1.9.1.2B *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;*
- *other data, as required.*

1.15B *Procedure Volumes*

A facility should perform a minimum of 100 invasive cardiac electrophysiology and/or device procedures annually to include the following:

- *Diagnostic Electrophysiology Testing and Ablation: 50 procedures*
- *Device Implantation: 50 procedures*
- *Chronic Lead Extractions (if performed): 20 leads per operator*[10]
- *Left Atrial Appendage Occlusion (LAAO) by Device (if performed): 20 procedures*

Each member of the medical staff should interpret a minimum of 100 invasive cardiac electrophysiology procedures. Each member of the nursing and technical staff should assist in a minimum of 100 invasive cardiac electrophysiology 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 Cardiac Electrophysiology Standards from applying for accreditation.

Centers specializing in pediatric and adult congenital heart disease may need to perform a relatively large percentage of epicardial device implants to meet the challenges of patient size and anatomy. These cases may be counted in device implant quotas as long as the medical staff is directly involved with lead testing and patient care along with the surgeons. Similarly, operator experience for chronic lead extraction at many pediatric centers may be less than 20 cases per operator annually. It is recommended that pediatric and adult congenital lead extractions be performed at experienced centers.

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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.

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

1.1.1.1C procedure/test appropriateness;

1.1.1.2C medical record completeness and timeliness;

1.1.1.3C patient safety;

1.1.1.4C procedure outcomes including complications and adverse events;

1.1.1.5C technical quality and performance of the procedure (left atrial appendage occlusion [LAAO] by device only);

1.1.1.6C interpretive quality review;

1.1.1.7C data management (device clinic only).

(See Guidelines below for further recommendations.)

STANDARD – QI Oversight

1.2C The Medical Director, Nurse Manager, Technical Manager, Device Clinic 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.

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 are 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, CIED functionality and management, shock plan, 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 2.1.7C. All metrics need to be measured for a minimum of four cases per procedure type, where applicable and be reviewed every six months.[1,10]

2.1.1C Procedure/Test Appropriateness (for procedure-based interventions only)

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).

(See Guidelines on Page 76 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 1.14B.

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 Patient Safety

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

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

2.1.3.3C 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 are not limited to:

i. all procedural complications including all serious adverse events;
ii. patient and personnel safety must be evaluated to include, but not limited to:
- accuracy of patient identification;
- medication safety;
- infection control measures;
- staff (occupational) and patient radiation exposure monitoring according to state regulations and published guidelines where appropriate; and[11,18,19]

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- follow up of non-compliant patients and missed/late transmissions.

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

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 must 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 cardiac electrophysiology accreditation procedure type (testing and ablation, device implantation, chronic lead extraction, left atrial appendage occlusion [LAAO] by device), device clinic and be reviewed every six months.

2.1.5C Technical Quality and Performance of the Procedure (for Left Atrial Appendage Occlusion [LAAO] by Device Only)

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 is 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
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 cardiac electrophysiology accreditation procedure type every six months.

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2.1.6C Interpretive Quality Review

2.1.6.1C The facility must evaluate the quality and accuracy of the results of the cardiac electrophysiology procedure and/or post-procedural onsite and longitudinal remote monitoring of implantable devices, 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 when only one interpreting physician is present in the facility.

2.1.6.3C Interpretive quality review must be measured for a minimum of four cases per procedure type (testing and ablation, device implantation and chronic lead extraction, left atrial appendage occlusion [LAAO] by device, device clinic) and be reviewed every six months.

2.1.7C Data Management (Device Clinic Only)

2.1.7.1C The facility must evaluate device clinic reporting and data transmission and storage for standardization, completeness of procedure information and documentation in the medical record as required by Standard 1.10B.

2.1.7.2C Data management must be measured for a minimum of four cases per procedure type (device clinic) and be reviewed every six months.

Section 2C: Quality Improvement Measures *Guidelines*

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

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.*

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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 and 1.6.3.7B) must be reviewed during these meetings.

3.1.3C All relevant staff must participate in at least one meeting per year. All staff are responsible for the content discussed during the QI meetings; therefore, every attempt should be made to either attend in person, via web conference or teleconference. If unable to attend one of the two biannual meetings, the staff member is required to review the meeting minutes and document their attendance with one of the following: Medical Director, Nurse Manager, Technical Manager and/or an appointed QI committee member.

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

3.2.1C The Medical Director and medical staff must attend a minimum of one M&M conference per quarter related to cardiac electrophysiology.

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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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Appendix A

Medical Staff Required Training and Experience

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

The 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 cardiac electrophysiology procedures. The currently acceptable national society training standards are:

i. 2015 ACC/AHA/HRS Advanced Training Statement on clinical cardiac electrophysiology (A Revision of the ACC/AHA 2006 Update of the Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation and Cardioversion).[2]

ii. American College of Cardiology/American Heart Association 2006 Update of the Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardio-version: A Report of the American College of Cardiology/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training, developed in collaboration with the Heart Rhythm Society.[2]

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x. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction[31]

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

Fluoroscopy: Equipment and Instrumentation

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

2.1.7.1A 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 8 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/helpful-resources/sample-documents-repository.
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.

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Appendix B

Procedure Interpretation and Reports

Requirements for device measures, testing and program setting data:

1.7.1.4B Device measures, testing and program setting data, if applicable must include, but not limited to:

i. baseline rate and rhythm;

ii. for permanent pacemaker or implantable cardioverter defibrillator (ICD) including resynchronization therapy (CRT) the following as measured by the pacing systems analyzer (PSA) for each lead implanted;

a. for right atrial lead:
- atrial P wave in millivolts (mV);
- atrial capture threshold in volts (V) at given pulse width/duration in milliseconds (ms); and
- lead impedance in ohms (Ω).

b. for right ventricular lead:
- R-wave amplitude in millivolts (mV);
- ventricular capture threshold in volts (V) at given pulse width/duration in milliseconds (ms);
- lead impedance in ohms (Ω); and
- no diaphragmatic stimulation at ___ volts (V), when appropriate.

c. for left ventricular lead:
- R-wave amplitude in millivolts (mV) as applicable per device;
- left ventricular capture threshold in volts (V) at given pulse width/duration in milliseconds (ms);
- lead impedance in ohms (Ω); and
- no diaphragmatic stimulation at ____ volts (V).

iii. defibrillation testing (DFT), when performed:
- method of induction;
- detection and termination result in joules (J);
- defibrillation threshold in joules (J); and
- high voltage impedance(s) in ohms (Ω).

iv. device programmed setting data (all that apply to implanted device):
- pacemaker bradycardia settings:
  - pacing mode;
  - lower rate in beats per minute (bpm); and
  - upper rates in beats per minute (bpm).
- atrial tachycardia/fibrillation settings:
  - detection rate in (atrial) beats per minute (bpm);
  - atrial anti-tachycardia therapy as programmed.
- ventricular tachycardia/fibrillation settings:
  - detection rate ranges of tiers of monitoring and/or therapies in beats per minute (bpm);
  - ventricular anti-tachycardia pacing therapy as programmed; and
  - cardioversion/defibrillation therapies in joules (J).

v. device measured data for each lead implanted:
- for right atrial lead:
  - atrial P wave in millivolts (mV);
  - atrial capture threshold in volts (V) at given pulse width/duration in milliseconds (ms); and
  - lead impedance in ohms (Ω).
- for right ventricular lead:
  - R-wave amplitude in millivolts (mV);
  - ventricular capture threshold in volts (V) at given pulse width/duration in milliseconds (ms); and
  - lead impedance in ohms (Ω).
- for left ventricular lead:

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- R-wave amplitude in millivolts (mV) as applicable per device;
- left ventricular capture threshold in volts (V) at given pulse width/duration in milliseconds (ms); and
- lead impedance in ohms (Ω).

vi. other data, as required.

Comment: Sidedness must be indicated for all lead positions and measurement sample sites for testing when referring to data described in this section (Anatomical description(s) for lead position and measurement sample sites may be used in cases of complex congenital heart disease).

Comment: If Defibrillation Testing (DFT) is performed during an ICD procedure, measures listed (Standard Section 1.7B) shown above must be included in the report.

1.11.8B Triage applicable evaluation findings to include, but not limited to: [37]

1.11.8.1B CIED functioning abnormalities, when applicable;

i. loss of capture:
   a. physiologic;
   b. non-physiologic; and
   c. automated capture.

ii. lead fracture:
   a. lead failure;
   b. physiologic threshold increase;
   c. insulation failure;
   d. polarity/lead safety switch; and
   e. high-voltage/low-voltage.

iii. undersensing:
   a. inappropriate tracking;
   b. physiologic loss of capture (atrial, ventricular);

iv. oversensing:
   a. far-field;
   b. electromagnetic interference (EMI);
   c. myopotentials;
   d. T-wave;
   e. inappropriate mode switching;
   f. lead integrity alert;
   g. t-wave oversensing; and
   h. loose set screw.

1.11.8.2B stimulation abnormalities, when applicable:

i. failure to initiate myocardial depolarization; and
ii. pacemaker-mediated tachycardia.

1.11.8.3B rhythms/conduction abnormalities of concern, when applicable:

i. atrial fibrillation/atrial flutter; and
ii. ventricular tachycardias:
   a. polymorphic;
   b. monomorphic;
   c. torsades de pointes;
   d. non-sustained;
   e. sustained;
   f. 1:1 VA conduction; and
   g. dual tachycardia.
iii. supraventricular tachycardias:
   a. atrial tachycardia;
   b. atrioventricular (AV) node reentrant tachycardia; and
   c. long R-P tachycardia.

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iv. sinus tachycardia;
v. atrio-ventricular (AV) block:
    a. Mobitz 1;
    b. Mobitz 2; and
    c. complete.
vi. normal sinus;
vii. sinus arrhythmia:
    a. sinus pause/arrest; and
    b. nocturnal pause.
viii. junctional rhythm;
ix. aberrancy;
x. premature ventricular contraction (PVC);
xi. premature atrial contraction (PAC);
xii. ventriculoatrial (VA) conduction;

1.11.8.4B battery depletion, when applicable:
i. elective replacement indicator (ERI)/recommended replacement time (RRT);
ii. end of life (EOL);
iii. transmission interval;
iv. capacitor reform time;
v. battery voltage curve; and
vi. device projected battery longevity or battery voltage.

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Appendix C

Quality Improvement Measures

Requirements for safety and procedural outcomes:

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

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

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

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

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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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