

2015

ACE Standards

*for Electrophysiology (EP) and Implantable
Cardioverter Defibrillators (ICD) Accreditation*



Accreditation for Cardiovascular Excellence
Quality in Invasive Cardiovascular Care

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1. STANDARDS: Facility Related

A variety of procedures are now performed in the electrophysiology (EP) laboratory. These include, but are not limited to diagnostic and therapeutic procedures with various medications and device implantation. Depending on local needs, some laboratories may also be used for diagnostic and therapeutic coronary or peripheral procedures. The standards herein relate to the core functions of all EP labs specifically diagnostic electrophysiology and device implants. Separate standards exist specifically for other cardiac and peripheral catheter based procedures and are being developed for other procedures such as valvular interventions and structural heart disease interventions performed in the modern catheterization laboratory.

1.1. Each hospital department or section (cath lab, EP lab) performing EP and ICD procedures must document that they have the resources to perform the procedure in a safe manner.¹

1.2. Equipment

- 1.2.1. It is recommended that each EP laboratory have high-quality fixed fluoroscopic equipment, recording systems, emergency equipment, and anesthesia equipment.
- 1.2.2. Advanced physiologic monitoring with real-time and archived physiologic, hemodynamic and rhythm monitoring equipment with support staff capable of interpreting results and responding appropriately.
- 1.2.3. Large inventory of disposable supplies for vascular access and complication management.
 - 1.2.3.1. The inventory should include devices and drugs to assist in the management of emergent complications including allergic reactions, arterial thrombosis, thromboembolism or vessel rupture and dissection, pneumothorax and cardiac tamponade.
 - 1.2.3.2. All staff will be trained in the appropriate use of these devices.
- 1.2.4. Emergency management equipment and systems must be readily available in the EP suite. This includes resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation, and personnel familiar with their indications and use, in addition to emergency trays for pericardiocentesis, thoracentesis and thoracotomy.
- 1.2.5. There must be a process documenting routine preventive maintenance and testing of laboratory equipment, including a comprehensive radiation safety program such as outlined by The Society for Cardiovascular Angiography, The Heart Rhythm Society, and/or the American College of Cardiology.
- 1.2.6. The facility to be used for device implantation, must be an appropriate facility with Operating Room grade sterile technique. This includes appropriate ventilation with appropriate frequency of air exchanges appropriate floors, walls and flat surfaces, etc. The EP lab should be assessed by the facility's infection control department and the operating room/surgical leadership.

2. STANDARDS: Personnel Related

- 2.1. Each Department within the Institution (cath lab, EP lab) performing EP and/or ICD must have:
 - 2.1.1. A licensed, board-certified electrophysiologist in an appropriate specialty and/or sub-specialty as a Medical Director.
 - 2.1.2. A Technical Director (cardiovascular technologist, registered radiology technologist or registered nurse) with a minimum of 5 years of experience working in a cardiac catheterization or electrophysiology laboratory.
 - 2.1.3. A clearly delineated program for the initial granting of privileges with physician operators meeting the peer-reviewed Heart Rhythm Society, COCATS and ABIM training standards. The initial granting of privileges should be free of conflict of interest.
 - 2.1.4. A standard operating procedure for monitoring peri-procedural, in-hospital and 30-day outcomes.
- 2.2. Maintenance of physician privileges
 - 2.2.1. Physicians must obtain 30 hours of Category 1 continuing medical education credits per year period with a minimum of 20 hours in the field of arrhythmia diagnosis and therapy.
 - 2.2.2. The institution must have a defined process for re-credentialing which should be based on volume, outcomes, fulfillment of CME requirements and other quality parameters. There are currently no accepted standards for re-credentialing. These may develop over time and be implemented in a later version of these standards.
 - 2.2.3. Recertification criteria for individual practitioners should be decided by each institution but guidelines should include documentation for fulfillment of CME requirements as outlined in 2.2.1 and participation in at least 50% of Morbidity and Mortality and/or case review meetings.
 - 2.2.4. An operator's complication rates should not exceed those defined in publications by professional societies or the following thresholds¹².
 - 2.2.4.1. Mortality $\leq 1\%$
 - 2.2.4.2. Stroke $\leq 1\%$
 - 2.2.4.3. Major complications: emergency surgery, transfusion, cardiac arrest, heart failure, cardiac perforation, tamponade, air embolism, pneumothorax, vascular complication requiring surgical intervention
 - 2.2.4.4. Minor complications: hematoma, infection, venous thrombosis
 - 2.2.5. Hospital privileges and state licensing should be maintained throughout the period of certification for all operators. Any loss of either hospital privileges or state license shall be reported to ACE with an explanation from the Medical Director or CEO, CMO or institutional leader at the facility.
 - 2.2.6. For adult laboratories, physicians must maintain ACLS certification and follow facility standards for radiation safety.

2.3. Other Health Care Professionals

- 2.3.1. Skilled allied health professionals in the laboratory (advanced practice clinicians, nurses and technicians) must be trained and experienced in evaluating patients before and after catheter-based interventional procedure. State requirements for performance and roles of personnel must be supplied and facilities will be reviewed for compliance based on these standards.
- 2.3.2. Documentation of training of nursing personnel in the recognition and management of acute cardiovascular syndromes and cardiac complications is required.
- 2.3.3. Documentation of training of support staff to interpret results from physiologic, hemodynamic and rhythm monitoring equipment.
- 2.3.4. All personnel with direct patient care responsibilities should be ACLS certified.

3. STANDARDS: Quality Assurance

- 3.1. A quality monitoring program must include a peer-review conference with randomly selected EP/ICD procedures reviewed for their indications, documentation, and complication, and a quality oversight committee to review outcomes and make privileging recommendations.
 - 3.1.1. All major complications should be reviewed.
- 3.2. A regularly scheduled quality monitoring conference must occur no less than quarterly. All operators must have documented participation in a minimum of 50% of the quality review meetings.
- 3.3. A cath lab/EP lab specific quality assurance (QA) monitoring program must be present and integrated with the facility quality improvement program (CQI) effort.
 - 3.3.1. A QA program should include structural, process and outcomes indicators.
 - 3.3.2. Structural indicators may include: a) credentialing and re-credentialing criteria, b) completion of accurate and informative reports, c) documentation of CME participation.
 - 3.3.3. Process indicators may include: a) quality of electrophysiology studies, b) completion of accurate and informative reports, d) total procedure and fluoroscopy times, e) radiation dose, and f) other criteria.
 - 3.3.4. Outcome indicators assessed should be part of an overall QA program.
- 3.4. The quality assurance program must include a peer-review process with 10% randomly selected therapeutic device procedures representing all operators performing cases. These should be reviewed for their indications and complications, and include a periodic review of all major laboratory complication rates. Operative reports for these random selected patients should be reviewed for completeness for requisite documentation (indication, description of procedure, informed consent, complications, fluoroscopy used, estimated blood loss, contrast used, model and serial number of all implanted leads and devices, final measurements on all leads, final device settings, etc.

- 3.5. The QA program must include an assessment of: a) an assessment of overall and cardiac complication rates for all types of procedures performed, b) an assessment of the indications for device implantation, and c) proportion of patients that received antibiotics prior to device placement, and d) appropriateness of timing of antibiotics (cephalosporin initiation no more than 60 minutes prior to procedure, OR vancomycin Initiation no more than 120 minutes prior to procedure).
- 3.6. The oversight committee should be empowered to identify the minimum case volume for primary operators to maintain privileges, as well as a threshold complication rate to trigger activation of measures for remediation or potential suspension of privileges.
- 3.7. Major events such as [30 day] Death, Major Stroke, heart failure, cardiac perforation and cardiac arrest rates should not exceed 1% of the patient volume, or established thresholds based on the most recent report from the ACC-NCDR ICD Registry where appropriate¹².

4. STANDARDS: Radiation Safety

- 4.1. All laboratories must have a radiation safety program. In addition to the state required mandates for equipment evaluations, this program must assure the following:
 - 4.1.1. The radiation safety program should be considered a component of the overall EP facility quality assurance (QA) process with the EP program QA individual(s) actively involved with this process.
 - 4.1.2. Each EP facility must establish a radiation safety education program either in conjunction with the hospital Health Physics Department/Medical Physicist and/or an outside consultant and/or assistance from a web-based tutorial. Documentation of this training must be provided. This program should have the following mandated components: a) initial training or verification of prior training for all physicians and staff using fluoroscopy in the peripheral intervention facility; b) annual updates on radiation safety; c) hands on training for new operators in a facility and existing operators on newly purchased equipment.
- 4.2. Patient radiation dose must be monitored throughout the case, with staff and physician interaction, and then recorded in the procedure report.
 - 4.2.1. This should include the fluoroscopic time (FT, min) and total air kerma at the interventional reference point (Ka, r, Gy) and/or air kerma area product (PKA, Gycm²). Peak skin dose should be included if technology permits its measurement.
 - 4.2.2. A follow up program should be in place for patients whose recorded total air kerma at the procedure reference point (Ka, r) is 5 Gy or greater, PKA of 500 Gycm², and/or fluoroscopy doses that exceed 60 minutes. This program should include the dose and a reason for this dose, patient notification, medical physicist/health physics involvement for Ka, r >10Gy, and a mechanism for patient follow up of potential adverse effects from radiation. Physician must wear radiation exposure badges, monthly dosages calculated, and yearly totals reviewed. The radiation safety officer is responsible for the monitoring of this process.

5. STANDARDS: Reporting of Results

- 5.1. The reporting standards of The Joint Commission (TJC) for operative procedures must be followed. These include:
 - 5.1.1. Preliminary procedure reports must be written or dictated immediately after the procedure. Final should be posted to the medical record within 72 hours.
 - 5.1.2. There must be enough information in the record immediately after the procedure to manage the patient throughout the post-procedure period. This information could be entered as the procedure report or as a hand-written operative progress note.
 - 5.1.3. If the procedure report is not placed in the medical record immediately after the procedure due to transcription or filing delay, then a progress note should be entered in the medical record immediately after the procedure to provide pertinent information for anyone required to attend the patient. Immediately after the procedure is defined as “upon completion of procedure, before the patient is transferred to the next level of care.”
 - 5.1.4. The procedure progress note should contain at a minimum information including: a) name of the operator, b) procedures performed and description of each procedure, c) findings, d) estimated blood loss, e) specimens removed if appropriate, f) complications, g) post-operative diagnosis, and h) recommendations.
- 5.2. All procedure reports at a facility should be individualized to the institution but be consistent with the HPS for structured reporting, standardized among operators and contain relevant content on each of the following topics:
 - 5.2.1. Patient demographics, primary and assisting operator(s) and supporting staff present and procedures performed.
 - 5.2.2. Indications for each component of the procedure (i.e. electrical conduction testing, etc.)
 - 5.2.3. Appropriate supporting pertinent history, physical findings, and laboratory findings.
 - 5.2.4. The time frame and procedural events with technical comments, for example, EP procedures performed and any issues of concern.
 - 5.2.5. Access site information and closure method.
 - 5.2.6. All catheters, sheaths, guide wires, and other equipment used should be reported in a procedural section.
 - 5.2.7. Drugs and doses given during the procedure, type and amount of radiographic contrast used, and estimation of radiation exposure should be included in the procedure report.
 - 5.2.8. A clear description of any complications or a positive statement that there were no apparent complications.

5.2.9. Minimum requirements for reporting the EP study and ablation are:

A description of indication, discussion of access (right femoral vein, left femoral vein, IJ, etc), sizes of sheaths in each vein, types of catheters used and their locations (high right atrium, coronary sinus, his bundle, RV apex, RV outflow), stimulation, burst, extrastimuli, arrhythmia induction, maneuvers performed during arrhythmia (entrainment, HIS synchronous PVCs, etc). Assessment of AV nodal function antegrade and retrograde including assessment of dual AV nodal physiology, AV nodal ERP, Wenckebach cycle length, presence of retrograde conduction, assessment of antegrade and retrograde decremental and midline conduction, assessment of antegrade and retrograde bypass tract conduction, a description of induced arrhythmia, post-EP study diagnosis, ablation catheter, region of ablation, post-ablation EP study results (assessment of persistent inducibility, block in cavotricuspid conduction, loss of dual AV nodal physiology, etc), anticoagulation used, pharmacologic agents used (isoproterenol, adenosine, etc), complications.

5.2.10. For Devices:

A description of indication, documentation of informed consent, description of procedure including access (cephalic, axillary, subclavian), leads including model and serial number and location they are placed (where in atrium and ventricle), documentation of complications, documentation of fluoroscopy used, documentation of estimated blood loss, documentation of contrast used, documentation of complications, final measurements on all leads, final device settings, etc.

5.3. Summary of major findings or diagnosis.

5.4. Disposition of the patient as a result of the procedure and comments, including plans for follow-up care including medical therapy, Chest X-ray prior to discharge, ICD and pacemaker testing, and anticipated further interventions/procedures.

6. STANDARDS: Patient Indications

6.1. The indication for the EP testing and/or ICD implantation must be documented according to accepted societal standards and be consistent with published guidelines, expert consensus documents, or appropriate use criteria (AUC). Treatment for asymptomatic or non-threatening conditions is generally not warranted and must be fully supported by documented justification for performing the procedure.

6.1.1. There must be sufficient clinical information available in the procedure report and medical record to determine the indication for the procedure.

6.1.2. If the specific clinical scenario is not included in the AUC or if in the judgment of the physician the procedure is justified despite the AUC score, clear documentation of the reasoning should be included both in the medical record and in the procedure report.

6.2. Therapeutic indications based on New York Heart Association (NYHA) Functional Classification.

Class I – No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.

Class II – Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea.

Class III- Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.

Class IV - Unable to carry on any physical activity without discomfort. Symptoms of heart failure may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Ambulatory NYHA Functional Class IV: heart failure with 1) no active coronary syndrome, 2) no inotropes, 3) on guideline-directed medical therapy (GDMT).

- 6.3. Indications used for case review
 - 6.3.1. Unexplained syncope in patients at increased risk of sudden death , such as cardiomyopathy
 - 6.3.2. History of MI (> 40 days and several months after revascularization) and/or Ischemic CMP with EF < 30%
 - 6.3.3. Cardiomyopathy with EF <35% and class II to class III symptoms
 - 6.3.4. Select genetic conditions with increased risk of sudden death
- 6.4. Secondary prevention indication is for patients with resuscitated cardiac arrest or Sustained VT without a reversible cause
- 6.5. ICD is contraindicated in the following conditions:
 - 6.5.1. Life expectancy < 1 year
 - 6.5.2. Cognitive impairment with no health proxy
 - 6.5.3. Advanced psychiatric impairment
 - 6.5.4. Class IV heart failure and not a candidate for cardiac transplant, CRT or VAD
 - 6.5.5. Unresolved infection with risk for hematogenous seeding
 - 6.5.6. Ongoing IV drug abuse
 - 6.5.7. Noncompliance with medical therapy and follow-up
- 6.6. $\geq 90\%$ of cases should meet criteria for EP studies or ICD implantation
- 6.7. All treated patients should have an immediate and/or following day post-implant check and chest X-ray appropriate to the type of device placed.

7. STANDARDS: Patient Outcomes

7.1. Hospital-based outcomes, prior to discharge

7.1.1. Devices will be programmed in the EP laboratory and checked for response.

7.1.2. Procedural success rate should be $\geq 90\%$ of cases.

7.1.3. Obtain chest X-ray

7.2. Complications

7.2.1. Complications: Death, Stroke, cardiac perforation, cardiac arrest

7.2.1.1. Access site complications

7.2.1.1.1. Requires re-intervention or surgical correction

7.2.1.1.2. Thromboembolism

7.2.1.1.3. Infection requiring antibiotics or drainage

7.2.1.1.4. Results in prolonged hospital stay

7.2.1.1.5. Requires any transfusion of PRBCs or platelets

7.2.1.2. Major complications: , extravasation, pneumothorax, tamponade, stroke, coronary artery injury, air embolism, death, cardiac perforation, DVT, PE, infection requiring intervention, hematoma requiring intervention

7.2.1.3. Other procedure related complications, including cardiovascular or pulmonary compromise, radiation or other injury, and other events warranting clinical management or observation. Procedure related complications occur within 48 hours of the procedure or during the same hospitalization

7.3. Follow-up Outcomes to 90 days (3 weeks to 3 months post-procedure)

7.3.1. Symptomatic, functional, quality of life improvement

7.3.2. Lead dysfunction requiring invasive intervention

7.3.3. Wound healing

7.3.4. 90 Day Device related Adverse Events

7.3.4.1. Death

7.3.4.2. Myocardial Infarction

7.3.4.3. Stroke

7.3.4.4. Cardiac arrest

7.3.4.5. Infection

7.3.4.6. Bleeding

7.4. Follow-up Outcomes every 3 months through one year

7.4.1. Symptomatic improvements

7.4.2. Absence of arrhythmias

7.4.3. Wound healing

7.4.4. Device related Adverse Events

7.4.4.1. Lead dysfunction requiring invasive intervention

7.4.4.2. Infection requiring invasive intervention

7.4.4.3. Bleeding

7.5. Follow-up Outcomes 360 days

7.5.1. Symptomatic improvement

7.5.2. Absence of arrhythmias

7.5.3. Wound healing

7.5.4. 360 day Device Related Adverse Event

7.5.4.1. Lead dysfunction requiring invasive intervention

7.5.4.2. Infection requiring invasive intervention

7.5.4.3. Bleeding

Performance Metrics

As part of the ACE application, performance metrics from the NCDR ICD Registry Executive Summary will be reviewed. The specific performance metrics examined and their source are shown in the table below.

Performance Metrics	Source	Line
Proportion of patients with left ventricular systolic dysfunction (LVSD) who were prescribed ACE-I or ARB therapy	NCDR	4
Proportion of patients with prior MI prescribed beta-blocker therapy on discharge	NCDR	5
Proportion of patients with LVDS who were prescribed beta-blocker therapy on discharge	NCDR	6
Composite: Discharge Medications (ACE/ARB and beta blockers) in eligible ICD implant patients	NCDR	14
Guideline Metrics		
Proportion of patients that receive an ICD for class I, IIa, or IIb guideline indication	NCDR	12
Test - proportion of ICD/CRT-D patients that fulfill class I, IIa, or IIb guideline indications	NCDR	15
Test-proportion of ICD patients that fulfill class I, IIa, or IIb guideline indications	NCDR	16
Test-proportion of CRT-D patients that fulfill class, IIa, or IIb guideline indications	NCDR	17
Process Metrics		
Proportion of patients that receive antibiotics prior to the ICD implant or lead procedure	NCDR	7
Outcome Metrics		
Failure to successfully place coronary sinus/left ventricular lead (CRT-D implants)	NCDR	10
Incidence of hematoma (implant procedures)	NCDR	11
Incidence of death or major adverse event (implant procedures)	NCDR	13
Risk adjusted complications (all implants)	NCDR	18

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