Heart Rhythm Society Expert Consensus Statement on Electrophysiology Laboratory Standards: Process, Protocols, Equipment, Personnel, and Safety

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TABLE OF CONTENTS

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ABBREVIATIONS **CIED** = cardiovascular implantable electronic device; **CT** = computed tomography; **EP** = electrophysiology; **FDA** = U.S. Food and Drug Administration; **ICD** = implantable cardioverter-defibrillator; **MRI** = magnetic resonance imaging; **QA** = quality assurance; **QI** = quality improvement; **RF** = radiofrequency; **VT** = ventricular tachycardia (Heart Rhythm 2014;11:e9–e51)

Developed in collaboration with and endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Pediatric and Congenital Electrophysiology Society (PACES). Endorsed by European Heart Rhythm Society (EHRA), and Sociedad Latinoamericana de Estimulacion Cardiaca y Electrofisiologia (SOLAECE)-Latin American Society of Cardiac Pacing and Electrophysiology. EHRA endorses the recommendations of the expert consensus statement, with the exception of those statements specifically addressing US regulations. **Address correspondence:** David E. Haines, MD. E-mail address: dhaines@beaumont.edu.

1. Introduction

The modern electrophysiology (EP) laboratory is a complex environment providing an array of interventions for the diagnosis and treatment of heart rhythm disorders and is a result of many transformations over the last three decades. The EP field has witnessed rapid expansion in the number of therapeutic procedures treating a wide range of arrhythmias and in the new technologies available to perform these procedures. Because of the increasing complexity of equipment and procedures and an ever-expanding knowledge base, it was concluded that the field would benefit from a consensus document that would define the critical components and processes of a modern EP laboratory. To this end, the Heart Rhythm Society (HRS) convened a multidisciplinary team to review EP laboratory design, ergonomics, personnel, equipment, occupational hazards, and patient

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safety, as well as clinical and ethical issues related to diagnostic and therapeutic EP procedures. The goal is to provide physicians, administrators, and regulatory personnel with the recommended requirements for building, staffing, and running a modern EP laboratory to optimize patient outcomes, minimize patient risk, and provide a safe and positive environment for physicians and staff.

The writing committee was formed by the Scientific and Clinical Documents Committee of the HRS, with approval by the President of the HRS and the HRS Executive Committee. The composition of the committee was meant to represent the range of stakeholders in the EP laboratory. The choice of the writing committee members was in accordance with the HRS Relationships With Industry policy.[1] All members of the writing committee were required to fully disclose all potential conflicts of interest (see Appendix 1).

Relatively little published literature addresses the EP laboratory environment, staffing, and processes. Therefore, many of the statements in this document are the product of expert consensus by the writing committee and reviewers. For cases in which there were divergent opinions on a statement, a vote among writing committee members was taken, and if a two-third majority supported the statement, it was adopted in the document. The sections pertaining to pediatric and adult congenital heart disease were reviewed and approved by the Pediatric and Congenital Electrophysiology Society (PACES), a nonprofit organization dedicated to the treatment of arrhythmia disorders in children and individuals with congenital heart disease (CHD). The final document was approved by the Board of Trustees of the HRS. This document is directed to all health care professionals who design, manage, and/or work in the EP laboratory environment.

2. Evolution of the EP Laboratory

The field of clinical cardiac electrophysiology (CCEP) has grown from its origin as a field of clinical research for arrhythmogenesis to its present-day incarnation as an important specialty offering advanced therapies for a wide variety of disorders. Clinical EP laboratories emerged in the late 1960s, and by the early 1970s, formal fellowships had been established and EP laboratories were taking shape. First-generation EP laboratories often shared space with cardiac catheterization laboratories and were typically subordinate to coronary angiographic and hemodynamic procedures. When a space was dedicated for electrophysiological testing, it was often small, and fluoroscopy was delivered with portable C-arm units. These laboratories were sufficient for diagnostic EP studies and electropharmacological testing. Second-generation EP laboratories developed in the 1980s with the introduction of catheter ablation and cardiac implantable electronic devices (CIEDs) to the electrophysiologist's armamentarium. Pacemaker implantation was shifting from the domain of surgery to that of cardiac EP. With increasingly complex procedures being performed in EP laboratories, more space was allocated to new dedicated laboratories and fluoroscopy equipment began to be upgraded to systems commensurate with those used in cardiac catheterization laboratories.

The third generation of interventional cardiac EP has been driven by the success of catheter ablation and advanced device therapy. The precise anatomy and physiology of a wide variety of arrhythmias has been elucidated through the development of advanced mapping systems and improvements in ablation catheter technologies. Modern device therapy incorporates multimodal multisite pacing, sophisticated therapies for tachyarrhythmias, and advanced diagnostics. With the increasing complexity of EP procedures and equipment has come increasing sophistication of laboratory processes and greater demands on laboratory personnel. The cost and complexity of the modern EP laboratory now demands that standards are developed to ensure a high level of care.

3. Laboratory Environment

Laboratory Environment Recommendations

- Highly complex procedures or procedures on patients with certain conditions and comorbidities that are associated with higher procedural risk should not be performed in a freestanding laboratory (i.e., an EP laboratory that is not physically attached to a hospital).
- Emergency cardiovascular surgical support should 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 pericardial access.
- High-risk procedures in critically ill patients, such as ablation of ventricular tachycardia in patients requiring extracorporeal hemodynamic support, can only be safely performed in institutions offering comprehensive programs with active engagement from electrophysiologists, surgeons, intensivists, and anesthesiologists.

3.1. Procedure Room Options

There are multiple options and practice settings for performing EP and implantable device procedures. Medical centers may adopt one or more of the following laboratory operations for their practice. The choice among the following options involves a trade-off between increasing capability for procedure complexity and increasing construction and operating costs.

3.1.1. Dedicated EP Laboratory

In a dedicated EP laboratory, the staff space and procedure room space are separate from the cardiac catheterization laboratory and/or radiology laboratory, although the staff space and procedure room space often exist within a common area. The preparatory and recovery rooms are often shared with other subspecialties. Procedures that can be performed in this