Cardiac resynchronization therapy

Background

Cardiac resynchronization therapy (CRT) is a treatment for heart failure treatment that helps to correct dyssynchrony, or a mechanical discord between the beating of the two ventricles of the heart. According to the Heart Failure Society of America, over 550,000 Americans are diagnosed with heart failure every year, and nearly 300,000 deaths annually are attributed to heart failure.

CRT involves implanting a device to help synchronize the beating of the left and right ventricles. CRT pacing devices are similar to pacemakers in that they are battery-powered, electronic devices implanted under the skin. However, CRT devices differ from standard pacemakers because standard pacemakers have two wires, or leads, both implanted in the right side of the heart. A CRT device has at least three leads: one implanted in the left ventricle, one in the right ventricle, and one in the right atrium. In December 2011, the FDA approved the first four-lead CRT device.

There are two types of CRT devices. A CRT-P is a pacemaker device that detects dysynchrony and sends pulses to resynchronize the heartbeat. A CRT-D is an implantable cardioverter defibrillator (ICD) that monitors the patient’s heartbeat. After the CRT-D device is implanted, the cardiologist programs the device to deliver a shock to the heart if it begins beating too rapidly. Surgery to implant CRT-P and CRT-D devices is normally performed under local anesthesia.

There are a number of FDA-approved CRT devices on the market from several different manufacturers, and new devices frequently enter the market. Based on clinical studies showing that CRT can be effective for patients with milder signs of heart failure, the FDA is considering recommendations from its Clinical Advisory Committee that it broaden the population of patients for which the use of various CRT devices is approved.

Involved specialties

Electrophysiologists and cardiologists

Positions of specialty boards

**ABIM**

The American Board of Internal Medicine (ABIM) offers a certificate in the subspecialty of clinical cardiac electrophysiology. Physicians must already be board certified in internal medicine and must have earned a certificate in cardiovascular disease before entering the clinical cardiac electrophysiology training program.
Since completing the electrophysiology fellowship, candidates must have devoted at least 50% of their professional time to clinical cardiac electrophysiology in a variety of clinical settings, such as the electrophysiology laboratory (serving as the primary operator or as an assistant closely involved with data collection and analysis), emergency department, coronary care unit, operating room, and follow-up clinic.

The ABIM requires that candidates for certification in electrophysiology undertake 12 months of training in electrophysiologic studies both with a catheter and intraoperatively; catheter-based and other ablation procedures; and implantation of pacemakers and cardioverter-defibrillators (a minimum of 150 intracardiac procedures in at least 75 patients, of which 75 procedures are catheter-based ablation procedures, including post-diagnostic testing, and 25 are initial implantable cardioverter-defibrillator procedures, including programming). Procedures performed during training in cardiovascular disease may be counted toward fulfilling these requirements provided that they are adequately documented and are performed with supervision equivalent to that of a clinical cardiac electrophysiology fellowship.

Fellows also must perform the following exams and procedures (procedures performed during the general cardiology fellowship do not count toward this number):

- 150 electrophysiologic evaluations (interpretation or participation)
- 75 non-atrial fibrillation ablations
- 35 atrial fibrillation ablations
- 25 ICD implantations
- 25 CRTs (biventricular pacing)
- 25 dual-chamber pacemakers
- 30 pacemaker/device revisions
- 20 pacemaker/device interrogations

**AOBIM**

The American Osteopathic Board of Internal Medicine (AOBIM) offers a certificate in cardiology. Applicants must be American Osteopathic Association (AOA) board certified in internal medicine and must have completed a three-year training program in cardiology. The AOBIM also offers a certificate of added qualification in clinical cardiac electrophysiology. Eligible candidates must be board certified in cardiology and have completed an additional one-year AOA-accredited training program in clinical cardiac electrophysiology, and must pass a certification examination.

The AOBIM does not publish specific requirements regarding cardiac resynchronization therapy.

**IBHRE**

The International Board of Heart Rhythm Examiners (IBHRE), an independent affiliate of the Heart Rhythm Society (HRS), offers competency examinations to
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physicians. The examination is open to both fellowship-trained physicians and experienced physicians who have not had fellowship training in clinical cardiac electrophysiology, but have experience in the field and wish to have privileges to implant cardiac devices. According to the IBHRE, this allows experienced practitioners who are no longer eligible for board certification through the ABIM to obtain a certificate of competency in implanting and programming cardiac rhythm devices.

Applicants for the IBHRE Cardiac Rhythm Device Therapy Examination for Physicians must have accomplished one of the following:
➤ Completed a fellowship in cardiology (adult or pediatric).
➤ Completed a fellowship in clinical cardiac electrophysiology.
➤ Have demonstrated one year of direct, substantial involvement in the care of cardiac rhythm device patients, including a minimum of 100 device interrogations with reprogramming as needed. The devices must include pacemakers, implantable defibrillators, cardiac resynchronization devices, and implantable loop recorders/cardiac monitors.

Physician applicants must document their medical training and experience, and have a valid, unchallenged license to practice medicine in the United States.

Positions of societies, academies, colleges, and associations

ACC/AHA/HRS

The American College of Cardiology (ACC) and the American Heart Association (AHA) address training requirements and guidelines for pacemaker and ICD implantation in the report Task Force 6: Training in Specialized Electrophysiology, Cardiac Pacing and Arrhythmia Management. The HRS endorses the report, which was most recently revised in 2008.

The report describes three levels of training for cardiac pacing, arrhythmia management, and specialized electrophysiology. The basic premise of the report is that implantable devices are now so sophisticated that managing patients with the devices has become its own subspecialty. Although all cardiologists are trained in the basics of pacemaker operation and management of patients with implantable devices, the implantation and primary follow-up should be performed by a physician with specialized training in clinical cardiac electrophysiology.

The report describes Levels 1 and 2 as including basic cardiology training in which the physician acquires knowledge and experience in the diagnosis and management of bradyarrhythmias and tachyarrhythmias (Level 1) and noninvasive arrhythmia management techniques. In this training, physicians develop competence and proficiency in the diagnosis, treatment, and long-term care of patients with complex arrhythmias (Level 2). These basic levels of training include programming and follow-up management of all types of bradycardia pacing, biventricular pacing, and ICD systems.
At Level 2, trainees must function as the primary programming operators who interrogate, interpret, prescribe, and reprogram devices in at least 100 patients. Although Level 2 trainees must have significant exposure to invasive electrophysiology, ICDs, and the surgical aspects of arrhythmia control device implantation, Level 2 training by itself does not qualify the trainee to perform these invasive procedures.

Level 3 training involves specialization in clinical cardiac electrophysiology. After a physician meets the requirements of Level 1 and Level 2, he or she must complete one more additional year of training beyond the three-year cardiology training program. Level 2 and Level 3 trainees may choose to receive additional training in the surgical aspects of device implantation, which may be obtained concurrently or sequentially with Level 2 or Level 3 training, respectively. For cardiology trainees who elect to obtain proficiency in the surgical aspects of transvenous bradycardia device (i.e., pacemaker) implantation, previous or concurrent Level 2 training is required.

The pacemaker implantation training must include development of expertise in:

- Permanent atrial right and left ventricular lead and ICD lead placement
- Threshold testing and programming of devices
- Principles of surgical asepsis
- Surgical techniques of implantation
- Management of implant-related complications

Individuals receiving qualifying training in pacemaker implantation must participate as the primary operator—under direct supervision—in at least 50 primary implantations of transvenous pacemakers and 20 pacemaker system revisions or replacements. At least half of the implantations should involve dual-chamber pacemakers (CRT). The trainee must also participate in the follow-up of at least 100 pacemaker patient visits and acquire proficiency in advanced pacemaker electrocardiography, interrogation, and programming of complex pacemakers.

The trainee pursuing a career in clinical cardiac electrophysiology also has the option of obtaining expertise in the surgical aspects of pacemaker or transvenous ICD implantation, or both. The same amount of surgical experience with bradycardia pacemaker implantation is required and may be supplemented with surgical training for ICD implantation. If the Level 3 trainee chooses this option, he or she must participate as the primary implanter—under direct supervision—in at least 25 ICD system implantations and possess the appropriate skills in management and follow-up.

**HRS**

In 2004, the HRS published the clinical competency statement *Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices.* In the statement, the HRS addressed training requirements for physicians who
were already experienced in pacemaker implantation but had not completed a fellowship in clinical cardiac electrophysiology. This document outlined requirements for an alternate training pathway for such physicians, which expired in 2008.

In 2005, the HRS released an addendum, endorsed by the ACC, which stated in part:

> It is important to realize that even the extensive experience with pacemaker implantation combined with the most current device company-sponsored abbreviated ICD implantation courses does not constitute sufficient training to implant ICDs or provide adequate patient follow-up and that only those physicians with documented appropriate training should be credentialed to implant ICDs.

A letter from the board of directors of the HRS dated October 2008 (when the alternate training pathway expired) “strongly recommends” that all credentialing bodies follow the recommendations as set forth in the ACC/AHA document, Task Force 6: Training in Specialized Electrophysiology, Cardiac Pacing and Arrhythmia Management.

The letter also states that there may be some experienced cardiologists who have not completed a fellowship in electrophysiology and were not able to meet the requirements of the alternate pathway before it expired, but who wish to implant pacemakers and ICDs, including CRT devices. For such physicians, the HRS recommends taking a competency examination, and suggests that the exam offered by the IBHRE is an acceptable alternative for those physicians who do not qualify to sit for the ABIM exam.

For all cardiologists seeking privileges to implant pacemakers and ICDs, the HRS recommends the following minimum number of procedures performed:
- 10 temporary pacemakers
- 10 cardioversions
- 75 cardiac implantable electronic device (CIED) implantations (25 single chamber, 25 double chamber, 25 CRT)
- 30 CIED revisions/replacements
- 200 CIED interrogations/programmings

To maintain competence, the HRS suggests a minimum of 35 CIED implantations per year. To maintain competence in ICD, the physician must perform 10 ICD implantations per year and follow up on at least 20 patients per year.

**ACGME**

The Accreditation Council for Graduate Medical Education (ACGME) has established training standards for resident physicians. The ACGME requires that
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physicians obtain a complete a cardiovascular disease residency program as a prerequisite to electrophysiology training. The cardiovascular disease residency program is three years long, and must include:

➤ Four months in a cardiac catheterization laboratory
➤ Six months of noninvasive cardiac evaluations, which must include three months of echocardiography and Doppler, two months of nuclear cardiology, and one month of other non-invasive cardiac evaluations
➤ Two months of electrophysiology, pacemaker follow-up, and ICDs
➤ At least nine months of non-laboratory clinical practice activities

Clinical experience must provide fellows with formal instruction and an opportunity to gain experience. Fellows must demonstrate competence in the prevention, evaluation, and management of inpatients and outpatients with the following conditions:

➤ Chronic coronary heart disease
➤ Congestive heart failure
➤ Arrhythmias
➤ Acute myocardial infarction and other acute ischemic syndromes
➤ Lipid disorders
➤ Hypertension
➤ Cardiomyopathy
➤ Valvular heart disease
➤ Pulmonary heart disease and pulmonary embolism
➤ Peripheral vascular disease
➤ Infections and inflammatory heart disease
➤ Cardiovascular rehabilitation

Fellows also must have formal instruction and clinical experience in prevention, evaluation, and management of patients with adult congenital heart disease, pericardial disease, and cardiovascular trauma. In addition, fellows must demonstrate competence in performing:

➤ Elective cardioversion
➤ Insertion and management of temporary pacemakers (transvenous and transcutaneous)
➤ Programming and follow-up surveillance of permanent pacemakers
➤ Bedside right-heart catheterization
➤ Right- and left-heart catheterizations including coronary arteriography (at least 100 procedures)
➤ Exercise stress testing (at least 50 procedures)
➤ Echocardiography (perform at least 75, interpret a minimum of 150)
➤ Intracardiac electrophysiology studies
➤ Intra-aortic balloon counterpulsation
➤ Percutaneous transluminal coronary angioplasty
➤ Programming and follow-up surveillance of ICDs
➤ Pericardiocentesis
After successfully completing the three-year cardiovascular disease fellowship, the resident may apply for an additional fellowship year with a concentration in electrophysiology. According to the *ACGME Program Requirements for Graduate Medical Education in Clinical Cardiac Electrophysiology*, fellows also must have formal instruction and clinical experience, and competently perform the following skills:

- Noninvasive testing relevant to arrhythmia diagnosis and treatment
- Invasive electrophysiologic testing (an average of three or more per week, a minimum of 150 intracardiac procedures performed, and at least 75 studies related to supraventricular arrhythmia)
- Electrode catheter introduction and positioning
- Stimulating and recording techniques
- Measurement and interpretation of data
- Therapeutic catheter ablation procedures (a minimum of 75 including post-diagnostic testing; must be a mix of AV nodal reentrant tachycardia and accessory pathway modification, atrial tachycardia and atrial flutter, AV junctional ablation and modification, and ventricular tachycardia ablation)
- Implantation of cardioverter-defibrillators and pacemakers (minimum of 25 initial ICD and 50 pacemaker procedures)
- Device programming (minimum of 100 interrogations)
- Noninvasive programmed stimulation for arrhythmia induction
- Defibrillation threshold testing
- Final prescription of anti-tachycardia pacing and defibrillation therapies

**AOA**

The AOA oversees a fellowship program in osteopathic electrocardiology. Applicants first must complete fellowship training in cardiology, which is a two-year program of study that includes learning activities in preventive cardiology, risk factor reduction, management of lipid disorders, and cardiac rehabilitation. The general cardiology fellowship also requires fellows to obtain knowledge, skill, and experience in the following tests and procedures:

- 150 electrophysiologic evaluations
- Interpretation/participation in 75 non-atrial fibrillation ablations
- Interpretation/participation in 35 atrial fibrillation ablations
- Interpretation/participation in 25 ICD implantations
- Implantation of 25 CRT (biventricular pacing)
- Implantation of 25 dual-chamber pacemakers
- 30 pacemaker/device revisions
- 20 pacemaker/device interrogations
- 3500 electrocardiographic interpretations
- 150 ambulatory ECG monitor recording interpretations
- 200 exercise test interpretations, including 100 pharmacologic (dipyridamole, adenosine, and dobutamine) tests
- 100 diagnostic cardiac catheterizations
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➤ 150 complete (M-mode, 2D, and Doppler) echocardiographic examination interpretations
➤ 25 transesophageal echocardiographic intubations
➤ Interpretation of 100 complete (myocardial perfusion, function, and viability) cardiac nuclear imaging studies
➤ Insertion of 10 temporary pacemakers
➤ 10 cardioversions
➤ Functioning as the primary programming operator who interrogates, interprets, prescribes, and reprograms devices in at least 100 patients
➤ Participation in 50 permanent pacemaker insertions
➤ Interpretation of 25 cardiac magnetic resonance studies
➤ Interpretation of 50 cardiac CT studies
➤ Insertion of 10 intra-aortic balloon assist devices with subsequent clinical management and removal of the device

The AOA’s subspecialty fellowship in electrocardiology requires an additional year of specialized study. During the fellowship the physician must have training and experience in:
➤ Catheter and intra-operative mapping procedures
➤ Catheter and surgical ablations
➤ Trans-septal perforation techniques
➤ Insertion of single- and dual-chamber pacemakers and implantable defibrillators
➤ External cardioversion and defibrillation
➤ Diagnostic electrophysiology studies
➤ Implantation of biventricular pacing devices
➤ Cardiopulmonary resuscitation
➤ Outpatient monitoring of pacemakers, implantable defibrillators, and patients with chronic arrhythmias

Positions of subject matter experts

John M. Miller, MD
Indianapolis

John M. Miller, MD, is affiliated with the Krennart Institute of Cardiology and oversees the electrocardiology fellowship program and the Indiana University School of Medicine. Miller explains that although there are experienced cardiologists who took advantage of the alternate training pathway as set forth in the 2004 HRS guidelines and are qualified to implant pacemakers, the alternate training pathway has closed.

“Many grandfathered cardiologists implant pacemakers, but [grandfathered cardiologists] should not be implanting permanent devices without the additional training of an electrophysiology fellowship. Thoracic surgeons will occasionally
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place a left ventricular lead surgically when it can’t be achieved transvenously by an EP doc, but typically don’t do the whole implant themselves,” Miller says. For “invasive procedures such as diagnostic EP study and catheter ablation, you need an EP doc.”

He points out that there are a number of implantable devices on the market in the United States, and that all of the manufacturers provide some training on device function, programming, and troubleshooting. “Some [manufacturers] have animal labs where the physicians can practice implant techniques, but none of them offer training on live patients in the United States,” he says.

Miller suggests, and notes that the ABIM requires, that a physician perform at least 25 ICD implantations in order to achieve competence with the procedure. Once competence has been developed, Miller says that his institution requires 12 ICD implantations per year to maintain competence.

Adam Zivin, MD

Seattle

Adam Zivin, MD, is the director of cardiovascular electrophysiology at the Swedish Medical Center’s Heart and Vascular Institute in Seattle. He points out that device implantation is no longer a standard part of cardiology fellowship training, although there are still some practicing cardiologists who were trained in the past to do pacemaker implantation and who have been trained to do CRT-P procedures by the device manufacturers. However, Zivin also notes that the large majority of CRT patients are candidates for CRT-D rather than the more limited CRT-P, and therefore these cardiologists do only a small number of procedures.

“The reality is that who implants devices (pacemakers, ICDs, CRT) is changing. Certainly ICDs, with or without CRT, should only be implanted by cardiologists with specialized EP training. There is ample data out there showing better outcomes when ICDs are implanted by EP-trained cardiologists, and given the adequate supply of EP docs, there really is no reason for general cardiologists to be implanting ICDs anymore,” Zivin says.

Zivin explains that manufacturers of CRT devices run hands-on training programs, but he suggests that “for the most part the idea of a cardiologist being trained by a manufacturer to do a procedure has fallen out of favor.” In general, Zivin says, manufacturer-taught training is directed at electrocardiologists who already are competent to perform implantations, and the training tends to focus on the features, nuances, and capabilities of the particular device the manufacturer produces.
Positions of accreditation bodies

CMS

CMS has no formal position concerning the delineation of privileges for CRT. However, the CMS Conditions of Participation (CoP) define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.
The Joint Commission

The Joint Commission has no formal position concerning the delineation of privileges for CRT. However, in its *Comprehensive Accreditation Manual for Hospitals*, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

➤ Developing and approving a procedures list
➤ Processing the application
➤ Evaluating applicant-specific information
➤ Submitting recommendations to the governing body for applicant-specific delineated privileges
➤ Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
➤ Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

➤ The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
➤ Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
➤ Consistent application of criteria
➤ A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
➤ Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
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➤ A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested
➤ Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism
➤ A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)
➤ A process to determine whether there is sufficient clinical performance information to make a decision related to privileges
➤ A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws
➤ Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.
HFAP

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for CRT. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

DNV

DNV has no formal position concerning the delineation of privileges for CRT. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”
The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements

➤ Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status

➤ Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding privileges for CRT.

**Minimum threshold criteria for requesting privileges in CRT**

**Basic education:** MD or DO

**Minimal formal training:** Successful completion of an ACGME-/AOA-accredited residency in clinical cardiac electrophysiology, or successful passing of the IBHRE examination within the last 10 years, with completion of an HRS-sponsored or endorsed didactic course on ICDs and CRTs.

**Required current experience:** Demonstrated current competence and evidence of the performance of 25 CIED procedures in the past 12 months or completion of training in the past 12 months.
**References**

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

**Reappointment**

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism.

Demonstrated current competence and evidence of the implantation of at least 50 CIEDs in the past 24 months based on results of ongoing professional practice evaluation and outcomes.

In addition, continuing education related to CRT should be required.

**For more information**

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Krannezt Institute of Cardiology
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Website: www.medicine.iupui.edu/krannert

Society of Thoracic Surgeons
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Swedish Medical Center Heart and Vascular Institute
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