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RESCISSIONS

The following material is rescinded:

1. Manual

M-2 Part IV, Chapter 2 dated October 23, 1990

## CHAPTER 2. CARDIOLOGY

## 2.01 POLICY

It is the Department of Veterans Affairs (VA) policy that invasive cardiovascular procedures will be performed only in appropriately authorized and equipped laboratories, by experienced, credentialled and privileged staff. Individuals must be board-certified in internal medicine, cardiovascular diseases or radiology. Trainees must be directly supervised by a fully qualified staff member.

## 2.02 SCOPE

a. Routine cardiac catheterization, angioplasty, valvuloplasty, pacemaker insertions and electrophysiologic studies and treatments are performed in 71 VA medical center laboratories.

b. Trends in average performance over several years are followed to assess compliance with minimum performance requirements. The minimum number of total procedures for a catheterization laboratory is 300; the minimum number of left heart procedures is 250.

## 2.03 CARDIAC CATHETERIZATION LABORATORIES

a. Authority. VA's cardiac catheterization laboratories are governed by regulations that call upon VA and the Department of Defense (DOD) to minimize duplication and underuse of health-care resources, and provides VA, DOD, and Public Health facilities with authority to enter into agreements to "share" health-care resources (see M-1, Pt. I, Ch. 1, Sec. XI).

b. Staffing. Approximately five clinical Full-time Employees (FTE) are required to operate a catheterization laboratory performing the minimum number of procedures. An example is: one Chief, Catheterization Laboratory, who is a physician, two Registered Nurses (R.N.s), and two catheterization laboratory technicians). NOTE: The goal of VA is to achieve 500 procedures per year per lab.

## c. Opening a Catheterization Laboratory

(1) Demographic changes have determined where new facilities are opened.

(2) Approval for the concept must be obtained through Veterans Health Administration's (VHA's) formal planning process. The VA medical center Director then submits an application to VA Central Office, Medical Service. Entirely new laboratories will require availability of on-site cardiac surgery. NOTE: No new laboratories will be opened unless nearby Federal government laboratories are performing an average of 500 cases annually.

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d. Retaining a Catherization Laboratory. Once established, a laboratory will stay open as long as it conforms to the minimum performance requirements of VA and other guidelines which VA accepts. For persistently borderline performance, (in terms of numbers, or morbidity and mortality status) a VA Central Office site visit team will be sent to evaluate, prior to authorization of new equipment.

e. Closing a Catherization Laboratory. Established criteria are used to determine that a laboratory should be closed. The stages of closure begin with warning letters, then progress to site visits and formal recommendations through channels.

(1) Failure to achieve a minimal performance standard or to report required statistics may result in closure.

(2) Failure to retain or recruit appropriately trained and credentialed staff, unduly high morbidity or a change in the mission of a VA medical center, may result in closure.

(3) Laboratories may be phased out through not replacing their equipment. NOTE: Most catheterization laboratory equipment is replaceable after 8 to 10 years. Once the decision is made to replace equipment, serviceable devices and in some cases, lead-lined rooms, may be retained for electrophysiology or procedure rooms. This permits two rooms, but just one state-of-the-art angiography suite. VA medical centers performing 1,000 total procedures per year could justify two fully equipped new rooms for coronary angiography.

f. Incident Reports

(1) Complications must be recorded at the local laboratory if they occur within 24 hours of the cardiac catheterization or if they are attributable to the catheterization even if remote in time. EXAMPLE: A patient who undergoes an angioplasty and has complications including dissection, myocardial infarction and subsequent renal failure. After a prolonged Intensive Care Unit (ICU) course including hemodialysis, the patient dies. The death is to be listed as an angioplasty related death (complication of procedure). All episodes of surgery that the patient would not have had if the catheterization had not been performed are also listed as complications.

(2) The following list is the minimum for local laboratory record-keeping: NOTE: Other serious complications, (especially those discussed in a staff review, or morbidity and mortality conference) should be included.

(a) Death during or related to catheterization;

(b) Dissection;

(c) Transient ischemic attacks and/or stroke and/or paralysis and/or visual changes;

(d) Myocardial infarction or pulmonary edema within 24-hours of catheterization;

(e) Renal failure (contrast nephrotoxicity);

(f) Perforation and/or tamponade and/or rupture;

(g) Amputation and/or peripheral vascular surgery;

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- (h) Anaphylaxis;
- (i) Pseudoaneurysm and/or significant hematoma and/or fistula;
- (j) Hypotension, during and after procedure, requiring intra-aortic balloon pump or sustained therapy;
- (k) Local infection or inflammation, requiring drainage;

(l) Septicemia; or bacterial endocarditis; or thrombophlebitis, requiring more than 7 days of treatment;

(m) Unusual catheter problems as breakage or rupture;

(n) Bleeding of a nature requiring transfusion or surgery; and

(o) Ventricular fibrillation and/or a complete heart block.

#### 2.04 CORONARY ANGIOPLASTY

VA authorizes the use of percutaneous transluminal coronary angioplasty (PTCA) as an elective and emergent procedure in accord with the following regulations:

a. Eligibility. Only VA medical centers with on-site Cardiac Surgery Programs are eligible to perform elective angioplasty. Due to the nature of VA which includes in-house programs, contracts, and sharing agreements to provide cardiac surgery, VA recognizes circumstances that may merit an exemption. Formal application for an exemption must be made to Medical Service (111A), VA Central Office.

b. Requirements for Training. Many VA cardiologists perform invasive procedures at other institutions. VA requires only that the total number of cases for an individual angioplasty attending comply with nationally accepted guidelines (e.g., 75 per year). VA medical centers with insufficient volume to achieve such a total experience for the individual angioplasty operator should discontinue performing PTCA, unless an experienced angioplasty attending will directly supervise each case (e.g., a fully-qualified university or community affiliated attending, who is present in the cardiac catheterization laboratory).

#### 2.05 PACEMAKERS/IMPLANTABLE DEFIBRILLATORS

a. Registry. Veterans with pacemakers and other implantable devices are registered through the National Pacemaker/Device Registry at the VA Medical Center, Washington, DC.

(1) Currently, 98 VA medical centers implant about 1,000 permanent pacemakers are annually. NOTE VA medical centers must implant about 15 pacemakers per year to remain authorized (sufficient volume to keep current).

(2) Patients are followed locally for clinical care and reprogramming, and by telephone for surveillance.

(3) Patients with Automatic Implantable Cardioverter Defibrillators (AICDs) are followed by 21 VA medical centers. They are:

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Region I

New York  
Richmond  
Washington, DC

Region 2

Ann Arbor  
Columbia  
Hines  
Indianapolis  
Milwaukee  
Minneapolis

Region 3

Gainesville  
Houston  
Little Rock  
Miami  
Nashville  
Oklahoma City  
Tampa

Region 4

Salt Lake City  
San Diego  
San Francisco  
Tucson  
West Los Angeles

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## b. Pacemaker Selection

(1) Shipping and/or Returns. Pacemakers appear on the Federal Supply Schedule. Receipt of a pacemaker is accomplished by Acquisition and Materiel Management (A&MM), which maintains a record for pacemaker purchases and returns. Unused pacemakers will be exchanged for credit as authorized, and then deleted from the facility's inventory.

(2) Explants

(a) Explanted pacemakers, which are removed because of evidence of unexplained clinical failure or because of a Food and Drug Administration (FDA) recall, will be sent by the Chief, A&MM, of VA medical centers to the Eastern Cardiac Pacemaker Surveillance Center, VA Medical Center, 50 Irving Street, NW, Washington, DC, 20422. The explanted pacemaker should be accompanied by a completed VA Form 10-0049, Explanted Cardiac Pacemaker Prosthesis (ECP) Data. A shipping label and a request for reimbursement by the manufacturer must be provided.

(b) Explanted pacemakers removed due to replacement or cremation can be tested locally and returned to the manufacturer for credit or sent in accordance with subparagraph b(1). If an individual medical center lacks the capability to evaluate an explanted model, it should be returned as stated in subparagraph b(1).

(c) All VA medical centers need to ensure that credit is sought for explanted pacemakers still under warranty. If sent to the Eastern Pacemaker Surveillance Center, use the mailing label provided and include the request for reimbursement. A report on the operating characteristics of the explanted pacemaker will be sent to the originating VA medical center, to the manufacturer, and to the FDA. If evaluated at the individual medical center and found lacking, the pacemaker should be returned directly to the manufacturer for possible credit. All generators should be non-invasively analyzed so that VA can obtain credits toward new devices.

(3) Cremation. When an autopsy is performed, Standard Form (SF) 523, Authorization for Autopsy, will document the removal of the pacemaker. Otherwise, the Chief, Pathology Service, or designee, shall seek authorization (documented on SF 507, Clinical Record Report) from the family to remove the pulse generator. If the pulse generator is not removed from the body, the Death Certificate must clearly state its presence. For example:

NOTE: BODY CONTAINS A PACEMAKER WHICH INCLUDES A BATTERY OR POWER SOURCE.

(4) Other Equipment. Veterans electing pacemaker follow-up through VA will be supplied with attachments necessary for telephone surveillance (considered a prosthetic appliance). VA medical centers may not use any free monitoring

services offered by vendors or manufacturers directly or indirectly (this does not apply to loaned programmer equipment).

c. Pacemaker Surveillance Centers

(1) There are two pacemaker surveillance centers for telephone monitoring:

(a) The Eastern Pacemaker Surveillance Center, VA Medical Center, Washington, DC, serves pacemaker recipients East of the Mississippi River. It is the location of the National Pacemaker/Device Registry and will analyze explanted cardiac pacemakers as needed. For clinical issues call: FTS 8-700-921-8398 or 1-800-543-PACE (7223).

(b) The Western Pacemaker Surveillance Center, VA Medical Center, San Francisco, CA, serves pacemaker recipients West of the Mississippi River. For clinical issues call FTS 700-470-2079, or (415)-750-2077.

(2) The surveillance centers save time and effort for VA medical centers, as well as providing pacemaker expertise to remote and/or underserved areas on a device-specific basis.

NOTE: The VA medical center where the implant is performed or where the patient is followed, is responsible for making sure that stable pacing parameters are achieved.

(a) Telephone surveillance decreases the need for pacemaker clinic appointments. Most VA medical centers now defer telephone monitoring to the surveillance centers, which provide computerized reports back to the clinicians.

NOTE: Clinical follow-up is provided at VA medical centers or via fee-basis if not otherwise available locally.

(b) All veterans with pacemakers will continue to be offered telephone surveillance, from one of the two (Eastern or Western) pacemaker surveillance centers, even if they are no longer followed in a VA clinic.

(c) VA medical centers discharging patients from their clinics, or discontinuing clinics, must ensure that all pacemaker patients continue to be offered telephone surveillance. Any alternative method (to follow-up by one of the pacemaker surveillance centers) requires specific approval, with individual requests directed to Medical Service (111A), VA Central Office.