Department of Medicine and Surgery
Washington D.C. 20420

70-2199
#22735

Veterans Administration

In Reply Refer To:

'83 AUG 29 A10:44

August 26, 1983

Ms. Patricia C. Vacca
Material Licensing Branch
Division of Fuel Cycle and
Material Safety
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Ms. Vacca:

Thank you for your letter of August 8, 1983 in which you returned the Washington, DC VAMC's application for amendment to their pacemaker License No. SNM-1605.

We are pleased to inform you that the recision of the nuclear pacemaker portion of the VA program on explanted cardiac pacemaker prostheses has been accomplished. For your information, we are enclosing the original VA Circular 10-83-66, April 15, 1983, on this program in addition to the August 3, 1983 VA Telegraphic Message which deletes the nuclear pulse generators from the VA Circular 10-83-66.

We appreciate the time and patience which you have extended to the Veterans Administration on this issue.

Sincerely,

James J. Smith M.D.

JAMES J. SMITH, M.D.
Director, Nuclear Medicine Service (115)

Enclosures

Region I 08/29/83

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE	SECURITY CLASSIFICATION
VACO WASHINGTON DC	ACTION: P INFO:	
ACCOUNTING CLASSIFICATION	DATE PREPARED 8/3/83	FILE
FOR INFORMATION CALL		
NAME GERRIT W.H. SCHEPERS, M. D.	PHONE NUMBER 389-2550	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☒ MULTIPLE-ADDRESS

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO: DIRECTORS, ALVAMC, AND REGIONAL OFFICES WITH OUTPATIENT CLINICS, (REGIONAL DIRECTORS)

00/111 THIS IS SUPPLEMENT NO. 1 TO CIRCULAR 10-83-66 (DTD 8-16-83)

SUBJ: EXPLANTED CARDIAC PACEMAKER PROSTHESES (ECPP)

1. EFFECTIVE IMMEDIATELY, ON PAGE 2. OF PARAGRAPH 3.a.(2), DELETE THE WORDS "OR NUCLEAR PULSE GENERATORS" ON LINES 4 AND 5. 111/10A

2. THIS SUPPLEMENT EXPIRES ON APRIL 16, 1984. 111/10A

W. H. Schepers M.D.

SECURITY CLASSIFICATION	PAGE NO.	NO. OF PGS.
	1	1

JJCASTELLOT,SR., M.D.:vh 111 115 11B 8-16-83

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Veterans Administration
Department of Medicine and Surgery
Washington, D.C. 20420

Circular 10-83-66

April 15, 1983

TO: Regional Directors; Directors, VA Medical Center Activities, Outpatient Clinics, and Regional Offices with Outpatient Clinics

SUBJ: Explanted Cardiac Pacemaker Prostheses (ECPP)

1. Purpose. It is the intent of this circular to define new procedures to be followed in disposing of certain explanted cardiac pacemaker prostheses (ECPP), including all that are still under warranty.

2. Background.

a. Cardiac pacemaker prostheses (CPP) are acquired by the Veterans Administration with the understanding that their batteries have a limited life expectancy, but a presumption that these expensive prostheses are in other respects properly manufactured. VA medical centers explant in excess of one thousand CPP each year. Most of these are removed to be replaced by new CPP; some are also removed because they are no longer needed.

b. The manufacturers' warranties are required to be quite explicit and are summarized in the Marketing Center Decentralized Schedule governing the acquisition of CPP by VA medical centers. The VA is entitled to reimbursement for the unexpired time of the CPP warranty, if premature failure occurs. Until recently, there has been no mechanism by which explanted CPP could be tested other than by the manufacturers. The precise defects that lead to clinical failure of the CPP frequently are not reported to the VA. The recent establishment of the Cardiac Pacemaker Surveillance Centers (see Circular 10-82-72 and Professional Services Letter (11-82-27) has provided the VA with means to evaluate ECPP directly.

3. Procedures and Responsibilities.

a. Individual Veterans Administration Medical Facilities:

(1) Beginning April 1, 1983, all ECCP which are removed because of evidence of clinical failure while still under warranty will be sent by registered mail by the Chief of Supply of VA medical centers within Regions 1, 2, 3, and 4 to the Eastern Cardiac Pacemaker Surveillance Center (CPSC), 50 Irving Street, N.W., Washington, D.C. 20422, Attn: Ross D. Fletcher, M.D.

THIS CIRCULAR EXPIRES ON APRIL 16, 1984

Similarly, VA medical centers of Regions 5 and 6 will mail such ECPP to the Western CPSC, San Francisco, CA, Attn: Edward Gertz, M.D. Accompanying the ECPP should be a fully completed VA Form 10-0049. A copy of this form is attached so that you can reproduce it locally until such time as you receive an initial distribution from the Forms and Publications Depot. In addition, a shipping label to the manufacturer will be provided together with a request by the VA medical center for reimbursement against the unexpired portion of the warranty.

(2) ECCP with expired warranties should also be submitted if there is evidence of premature failure, if other unexplained malfunctions have occurred, or if they are dual chamber pulse generators or nuclear pulse generators. These will be analyzed for research purposes.

b. Cardiac Pacemaker Surveillance Centers: The centers will subject each ECPP received to non-invasive, non-destructive electronic analysis to determine the extent of depletion of the battery charge and the integrity of its electronic circuitry. The center staff will then forward the ECPP still under warranty to the manufacturer by registered mail in the same shipping container in which it arrived, using the mailing label provided and including the request for reimbursement. A report on the operating characteristics of each ECPP received will be sent to the originating VA medical center. The postal registration receipt will accompany this report for ECPP still under warranty. Copies of reports will also be sent to the manufacturer.

4. Reports. On conclusion of each fiscal year a summary report of findings will be sent by each CPSC to reach VA Central Office Medical Service (111) by the last work day of December each year. In turn, VACO Medical Service will disseminate the important findings to each health care facility and other appropriate offices, including the FDA and HHS Bureau of Device Regulation. RCS 11-67 is assigned.

5. Assistance with the implementation of this program may be obtained from Dr. Gerrit Schepers, VACO Medical Service, FTS 389-2550.

Attachment

DISTRIBUTION: COB: (10) only
SS (111) FLD: MA-5 each and RD, OC, & OCRO-2 each plus 200-8
EX: Box 44-6, Boxes 60, 54, 52-1 each & 63-5

W. J. JACOBY, JR., M.D.
Deputy Chief Medical Director

2.

EXPLANTED CARDIAC PACEMAKER PROSTHESIS (ECPP) DATA

Date_____

Referring VAMC _____ Station Ident. No._____

Address _____
_____

Contact Person _____ Phone No._____

Name of Patient _____ SSN_____

Date of Implant_____ Date of Explant_____

Reason for Explant:

_____ Premature Failure (under warranty); number of months remaining under warranty _____.

_____ As noted on CPSC Data Revision Form

_____ Other _____
_____

(Include pertinent rhythm strip or ECG in failure mode.)

Manufacturer of Pacemaker _____

Serial No. _____ Model No. _____

Acquisition Cost _____

Shipping Label to Manufacturer included?_____

Request for Reimbursement against unexpected portion of warranty included?_____

Warranty not applicable. Sent for research only _____

VAMCs from Regions 1, 2, 3 and 4 will mail this form and the ECCP to:

VA Eastern Cardiac Pacemaker Surveillance Center (688/005-2)
50 Irving Street, N. W.
Washington, D.C. 20422
ATTN: Ross D. Fletcher, M. D.

VAMCs from Region 5 and 6 will mail this form and the ECCP to:

VA Western Cardiac Pacemaker Surveillance Center
4150 Clement Street
San Francisco, CA 94121
ATTN: Edward Gertz, M. D.

Region I

SNM-1605
70-2199
VAMC, Waco.
TX

NO INCOMING

"OTHER AMENDMENT"

OK to process w/o
review by ADM/LFMB

P Wacca
8-30-83

22749