

SSINS. No.: 6835  
IN 86-59

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF INSPECTION AND ENFORCEMENT  
WASHINGTON, D.C. 20555

July 14, 1986

IE INFORMATION NOTICE NO. 86-59: INCREASED MONITORING OF CERTAIN PATIENTS  
WITH IMPLANTED CORATOMIC, INC, MODEL  
C-100 AND C-101 NUCLEAR-POWERED CARDIAC  
PACEMAKERS

Addressees:

All NRC licensees authorized to use nuclear-powered cardiac pacemakers.

Purpose:

This notice is to alert users of Coratomic, Inc. Model C-100 and C-101 nuclear-powered cardiac pacemakers of the manufacturer's recent warning of possible problems with certain units. The manufacturer recommends increased monitoring of patients with these units implanted. It is expected that licensees will review this information for applicability to their patients and consider actions, if appropriate. However, suggestions contained in this information notice do not constitute NRC requirements, therefore, no specific action or written response is required.

Description of Circumstances:

By letter dated March 14, 1986, the manufacturer, Coratomic, Inc., notified applicable attending physicians of possible problems with Model C-100 and C-101 plutonium-powered pacemakers that were manufactured between September 1974 and October 1977. During that time, "2CN potting material," a glue-like substance, was used in the construction of the pacers. The reversion of the 2CN potting material to a viscous form in some units has lead to a rate drop and to a higher-than-anticipated random transformer failure rate. Accordingly, Coratomic recommends that the monitoring of affected patients be increased to once every 3 months. The March 14 letter included a listing of affected patients.

Discussion:

There is no radiological hazard associated with the problem described in Coratomic's March 14, 1986 letter. However, this notice serves as a reminder that, as a condition of their license, licensees are required to follow the manufacturer's protocol and to notify the NRC within 10 days of loss of contact with a nuclear pacemaker patient. If you have any difficulty locating or contacting any affected patient, the NRC suggests you contact the manufacturer for assistance. However, since the Coratomic protocol, dated either August 1, 1974 or November 1, 1975, specifies in-person followup visits every 6 months for patients with Coratomic Model C-100 or C-101 pacemakers implanted for more than 6 months, you should have no difficulty in contacting affected patients.

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No specific action or written response is required by this information notice. If you have any questions regarding this matter, please contact the Regional Administrator of the appropriate NRC regional office or this office.

James G. Partlow, Director  
Division of Inspection Programs  
Office of Inspection and Enforcement

Technical Contact: J. R. Metzger, IE  
(301)492-4947

Attachment: List of Recently Issued IE Information Notices