

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
WASHINGTON, D.C. 20555

July 27, 1988

NRC INFORMATION NOTICE NO. 88-52: FAILURE OF INTRAUTERINE TANDEM OF FLETCHER  
SUIT APPLICATOR BRACHYTHERAPY DEVICES DURING  
PATIENT TREATMENT

Addressees:

Medical licensees.

Purpose:

This information notice is intended to provide information on the inspection of intrauterine tandem of Fletcher Suit Applicator brachytherapy devices for applicator weld corrosion and the proper sterilization procedures. It is expected that licensees will review this information for applicability to their brachytherapy activities and distribute this notice to responsible medical staff. Suggestions contained in this information notice do not constitute new NRC requirements, and no written response is required.

Description of Circumstances:

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health received eight reports since 1983 of incidents with Fletcher Suit Applicator intrauterine tandems. In each incident, the radioactive capsules were removed, but the closed end of the tandems separated from the applicator and remained in the patient during applicator removal. Additional radiographic and operating procedures were required to locate and remove the broken pieces. The failure is caused by weld joint corrosion. The corrosion may be due to improper cleaning before sterilization.

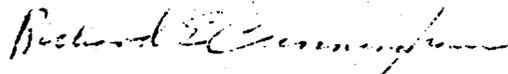
Discussion:

The Fletcher Suit Applicators can be used with either byproduct material or radium brachytherapy sources. The FDA believes that all Fletcher Suit Applicators should be inspected before each use, to ensure that the closed ends of the intrauterine tandem are secure. If they are not secure, the device should not be used. Cleaning the applicators with hydrogen peroxide or glutaraldehyde (Cydex) before autoclaving or cold sterilization may corrode the applicators' welds. The FDA recommends that the applicators be cleaned using only mild detergent and water, and then thoroughly rinsed with water before sterilization. The FDA also recommends that all applicators of similar design be checked, and the same cleaning instructions followed.

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No specific action or written response is required by this information notice. If you have any questions about this matter, please contact the person listed below or the appropriate NRC regional office.



Richard E. Cunningham, Director  
Division of Industrial and  
Medical Nuclear Safety  
Office of Nuclear Material Safety  
and Safeguards

Technical Contact: Donna-Beth Howe, NMSS  
(301) 492-0636

Attachment: List of Recently Issued NRC Information Notices

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LIST OF RECENTLY ISSUED  
 NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
88-46, Supplement 1	Licensee Report of Defective Refurbished Circuit Breakers	7/26/88	All holders of OLs or CPs for nuclear power reactors.
88-51	Failures of Main Steam Isolation Valves	7/21/88	All holders of OLs or CPs for nuclear power reactors.
88-50	Effect of Circuit Breaker Capacitance on Availability of Emergency Power	7/18/88	All holders of OLs or CPs for nuclear power reactors.
88-49	Marking, Handling, Control, Storage and Destruction of Safeguards Information	7/18/88	All holders of OLs or CPs for nuclear power reactors and all other licensed activities involving a formula quantity of special nuclear material.
88-48	Licensee Report of Defective Refurbished Valves	7/12/88	All holders of OLs or CPs for nuclear power reactors.
88-47	Slower-Than-Expected Rod-Drop Times	7/14/88	All holders of OLs or CPs for PWRs.
88-46	Licensee Report of Defective Refurbished Circuit Breakers	7/8/88	All holders of OLs or CPs for nuclear power reactors.
88-45	Problems In Protective Relay and Circuit Breaker Coordination	7/7/88	All holders of OLs or CPs for nuclear power reactors.
88-44	Mechanical Binding of Spring Release Device in Westinghouse Type DS-416 Circuit Breakers	6/24/88	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License  
 CP = Construction Permit