

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

August 13, 1997

NRC INFORMATION NOTICE 97-64: POTENTIAL PROBLEMS ASSOCIATED WITH
LOSS ELECTRICAL POWER IN CERTAIN
TELETHERAPY UNITS

Addressees

All U.S. Nuclear Regulatory Commission medical teletherapy licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to a potential problem associated with loss of electrical power in the Theratron 1000 teletherapy unit manufactured by Theratronics International, Limited. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action or written response is required.

Description of Circumstances

An Agreement State licensee notified the State authorities that a misadministration had occurred during a teletherapy treatment. Specifically, while a patient was being treated, a thunderstorm resulted in a loss of electrical power twice during the treatment period. A hospital technologist reset the machine both times to allow treatment continuation. When the treatment ended, the patient commented that the wrong site may have been treated. The technologist then noticed that the light field was not aligned to the intended treatment site.

The hospital's Radiation Safety Officer and technologist were able to recreate the problem only when the technologist was lying on the table in the position that was occupied by the patient being treated and power was interrupted. The table subsequently moved approximately 20 centimeters (8 inches) in the longitudinal direction. The licensee then calculated that the patient received approximately 130 rads to the wrong treatment site. The hospital notified the manufacturer, Theratronics, of the event. After an investigation, the manufacturer concluded that the licensee had not operated the teletherapy unit in accordance with the operating instructions. The manufacturer, however, noted the problem and flagged the operating instructions for possible improvement during the next general revision of the operator's manual.

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Updated on 970821

PDR I+E NOTICE 97-064 970813



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Discussion

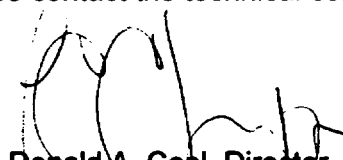
All licensees are reminded of the importance of ensuring the safe performance of licensed activities in accordance with NRC requirements, the requirements of their licenses, and the instructions in the manufacturer's operator's manual. Section 4.7 of the operator's manual discusses actions that must be taken if there is a loss of electrical power. These actions include removing the patient from the treatment room and realigning before resuming treatment. In addition, Section 4.7 contains a warning that states:

[i]f Table 23T is equipped with the 'free float' option, when the power is off, the lateral and longitudinal motions will be free. Take care to prevent injury when unloading the patient.

Users of the Theratronics 1000 teletherapy unit are reminded that they should clearly understand the manufacturer operator's manual. Additionally, in cases where questions or problems arise concerning unit use, users should contact the manufacturer and should remember the potential for causing a significant radiation exposure to unintended sites.

Licensees should also be aware that medical device user facilities are now subject to mandatory Food and Drug Administration (FDA) adverse event reporting requirements for medical devices. Information concerning FDA's mandatory reporting requirements can be obtained by contacting the Center for Devices and Radiological Health, Office of Surveillance and Biometrics, Division of Surveillance Systems at (301) 594-2735. Since the FDA mandatory reporting requirements may not be applicable to all medical device events, FDA also depends on information voluntarily provided by device users because they are often the first to recognize medical device related hazards. Any concerns that licensees may have pertaining to the safety or quality problems associated with medical devices can be voluntarily reported to the FDA by calling MedWatch at 1-800-FDA-1088. Voluntary reports can be submitted anonymously.

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contact listed below.



Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Nader Mamish, NMSS
301-415-6316
E-Mail: nlm@nrc.gov

Coordinated with Theratronics & FDA

Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

Attachment filed in Jacket

LIST OF RECENTLY ISSUED
 NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
97-61	U.S. Department of Health and Human Services Letter, to Medical and manufacturers/distributors, on the Year 2000 Problem	08/06/97 Device Manu-	All U.S. Nuclear Regulatory Commission medical licensees, veterinarians, butors of medical devices
97-58	Mechanical Integrity of In-Situ Leach Injection Wells and Piping	07/31/97	Holders of and Applicants for Licenses for In-Situ Leach Facilities
97-57	Leak Testing of Packaging Used in the Transport of Radioactive Material	07/30/97	Suppliers and users of packaging for the transportation of radioactive material required to perform packaging leak tests
97-56	Possession Limits for Special Nuclear Material at the Environcare of Utah Low-Level Radioactive Waste Disposal Facility	07/28/97	All licensees authorized to possess special nuclear material
97-55	Calculation of Surface Activity for Contaminated Equipment and Materials	07/23/97	All Uranium Recovery Licensees
97-51	Problems Experienced with Loading and Unloading Spent Nuclear Fuel Storage and Transportation Casks	07/11/97	All holders of OLs or CPs for nuclear power reactors Designers and fabricators of independent spent fuel storage installations All holders of or applicants for licenses to operate ISFSIs
97-50	Contaminated Lead Products	07/10/97	All U.S. Nuclear Regulatory Commission licensees

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
97-63	Status of NRC Staff's Review of BWRVIP-05	08/07/97	All holders of OLs or CPs for boiling water reactors
97-62	Unrecognized Reactivity Addition During Plant Shutdown	08/06/97	All holders of OLs or CPs for nuclear power reactors
97-61	U.S. Department of Health and Human Services Letter, to Medical Device Manufacturers, on the Year 2000 Problem	08/06/97	All U.S. Nuclear Regulatory Commission medical licensees, veterinarians, and manufacturers/distributors of medical devices
97-60	Incorrect Unreviewed Safety Question Determination Related to Emergency Core Cooling System Swapover from the Injection Mode to the Recirculation Mode	08/01/97	All holders of OLs or CPs for pressurized-water reactors
97-59	Fire Endurance Test Results of Versawrap Fire Barriers	08/01/97	All holders of OLs or CPs for nuclear power reactors
97-58	Mechanical Integrity of In-Situ Leach Injection Wells and Piping	07/31/97	Holders of and Applicants for Licenses for In-Situ Leach Facilities

OL = Operating License
CP = Construction Permit

Discussion

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Coordinated with Theratronics & FDA

Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

DOCUMENT NAME: 97-64.IN

OFC	IMOB		NMSS*		IMOB		IMOB		IMAB		IMNS	
NAME	NMamish/II		EKraus-Fax		PHolahan		JPiccone		LCamper		DCool	
DATE	7/14/97		7/14/97		7/28/97		7/28/97		7/30/97		8/01/97	

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Coordinated with Theratronics & FDA

7/11/97 (NH)

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2. List of Recently Issued NRC Information Notices

DOCUMENT NAME: G:TELEETHER.NM

OFC	IMOB	C	NMSS*	IMOB	IMOB	IMAB	IMNS
	(NH) NMamish/II		EKraus-Fax	(NH) PHolahan	JPiccone	(NH) LCamper	(NH) DCool
DATE	7/14/97		7/14/97	7/28/97	7/19/97	7/30/97	8/1/97