

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

December 24, 1996

**NRC INFORMATION NOTICE 96-72: UNDETECTED FAILURES THAT MAY OCCUR
DURING PATIENT TREATMENTS WITH
TELETHERAPY DEVICES**

Addressees

All teletherapy licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to a recently reported failure of an AECL Theratron 780 teletherapy device to place the source in the exposure position during patient treatment, and the potential for similar failures in all older AECL teletherapy devices that were manufactured prior to 1985. These include the Theratron T765, T80, and T60 model numbers, and the Eldorado E78, E76, E8, and E6 model numbers. 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 nor written response is required.

Description of Circumstances

On November 29, 1996, a licensee's teletherapy physicist notified NRC that he was experiencing electrical problems with an AECL Theratron 780 teletherapy unit. On November 27, 1996, the licensee's radiation therapy technologist observed that the cobalt-60 teletherapy source was not in the exposure (beam-on) position during a patient treatment, even though the treatment timer was running. The running treatment timer was an indication of in-progress patient treatment. However, the beam-on indicator light was not illuminated, nor was the room radiation monitor indicating the presence of radiation. Thus, the information provided by the operating treatment timer conflicted with that from both the beam-on indicator and room radiation monitor. Upon observation of this problem, the

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treatment was terminated by licensee staff. When the teletherapy physicist subsequently evaluated the control panel operation he discovered a sporadic failure of the source to move to the exposed position, despite normal operation of the treatment timer.

On December 2, 1996, a service representative from Theratronics International Corporation arrived at the licensee's site. The service representative concluded that a loose wire connection, between the timer and the solenoid driver circuit board, was causing a sporadic circuit interruption which, in turn, prevented the activation of the driver necessary to move the source into the exposed position. The control console lights were found to be functioning normally; however, since the timer was not connected to any source position indicators, it continued to run even though the source was not in the exposed patient treatment position. Following repair of the loose wire connection to the circuit board the Theratronics service representative determined the unit was fully operational.

The device subsequently failed again on December 9, 1996, in a manner similar to that of the previously reported November 27, 1996, failure. This second failure has been attributed to a faulty solenoid driver circuit board, which was replaced by the Theratronics service representative. The first test of the unit, with the replacement circuit board in place, also resulted in the same system failure. However, neither the service representative or inspectors from both the Food and Drug Administration (FDA) and NRC have been able to reproduce this latest failure following replacement of the circuit board. Thus, the root cause of these failures has yet to be determined and efforts are continuing to make this determination.

Discussion

Review of this incident reveals that the malfunctioning unit was an early model Theratron 780 using a single channel timer. These single channel timers can be of either mechanical or digital designs. With this type of timer, originally installed on all AECL/Theratronics teletherapy units built before 1985, patient treatments are initiated by starting the treatment timer which, in turn, generates the signal to move the source to the exposed treatment position. If, for any reason, the source fails to move to the exposed treatment position, the timer will continue to run without interruption. This would result in the patient receiving less than the intended dose for that treatment fraction. Additionally, this can occur not only upon the initiation of treatment, but at any time the source exposure signal pathway is interrupted. Potential harm to the patient could occur if the failure of the source to move to the fully exposed treatment position is not observed, and subsequently corrected, by the licensee.

Since these older generation devices have this known single-point failure mode, it is important that licensees be especially vigilant in monitoring all status information available on the initiation, and throughout the course, of treatment. These would include not only the

timer count down, but the source position indicators and, if appropriate, the room radiation monitor alarm output. The illumination of the "Beam On" indicator does not necessarily mean that the source is in the exposure position, but merely indicates the source is not in the fully shielded position.

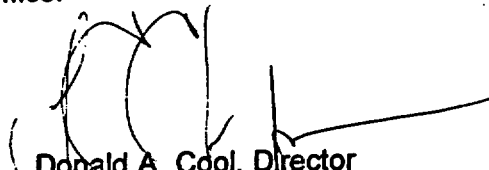
For the older (prior to 1985) AECL/Theratron devices with single channel timer units, the manufacturer presently offers a replacement dual channel timer of more recent design. Since some of these units may have been refurbished by other vendors, they may no longer carry the AECL/Theratron identification. If you have any questions concerning whether or not your unit is susceptible to this failure, contact either your service provider or refurbisher. The replacement timer is designed to operate quite differently than the older single channel timers it is intended to replace. Had this dual channel timer upgrade been installed, it is likely that the failure of the device to move the source into the fully exposed treatment position would have been more readily detected by the licensee and the potential for undetected patient underexposures reduced.

The vendor (Theratronics International Corporation) has informed NRC that it intends to notify all its customers having these older single-timer units, advising them of the potential problems and the vendor's recommended corrective actions. A copy of this vendor's notification is attached (Attachment 1). Licensees should contact the vendor directly with questions related to the notification.

Licensees should consider increasing their preventive maintenance procedures, replacement of parts, and upgrading of components (when available) for older devices, such as these teletherapy units, that may be approaching the end of their safe useful life. When considering options, licensees may wish to consider human factors studies that indicate that people are poor at detecting intermittent or infrequent failures, particularly if one operational indicator, such as the treatment timer, is monitored more closely than others.

Licensees should also be aware that medical device user facilities are now subject to mandatory 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 nor written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate NRC regional office.



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

Technical Contact: Robert L. Ayres, NMSS
(301) 415-5746
E-mail: rxa1@nrc.gov

Attachments:

1. Theratronics Customer Notification
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

Attachments filed in Jacket

December 10, 1996

Dear Theratron Customer,

**SUBJECT: REMINDER FOR SINGLE-CHANNEL TIMER UNITS OF
PRECAUTIONS IN THE OPERATOR'S MANUAL**

Model: _____

S/N: _____

Theratron units shipped prior to 1985 included single-channel timers, either mechanical or digital. Both of these models are designed to begin their timing sequence from the source-on command, rather than directly from the source transit drawer switches as in the more recent Theratron models. With these older single-channel timers, an electrical or mechanical problem in the source mechanism, should it go unnoticed, could affect the accuracy of treatment time.

Single-channel timers have been in use for more than thirty years and reports of problems have been very rare with no reports of significant dose misadministration. Users of units having single channel timers, however, are reminded of the following standard operating precautions:

1. As is explained in the Operator's Manual, observe the operation of the Source Position Indicator lights on the control console and above the treatment room door while treatment is in progress.
2. Follow daily start-up procedures and periodic maintenance instructions outlined in the Operator's Manual, and investigate any problems promptly.

Kits are available to install the current Dual Timer on older Theratron models, which will improve timer accuracy and reliability. Please contact Theratronics for price and delivery information at 1-800-826-2258 or 1-800-267-7230.



E.S. Martell
Vice President
Quality Assurance and Regulatory Affairs

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(613) 591-2100
Fax (613) 592-3816

**LIST OF RECENTLY ISSUED
 NMSS INFORMATION NOTICES**

Information Notice No.	Subject	Date of Issuance	Issued to
96-70	Year 2000 Effect on Computer System Software	12/24/96	All U.S. Nuclear Regulatory Commission licensees, certificate holders, and registrants
96-66	Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators	12/13/96	All U.S. Nuclear Regulatory Commission Medical Use Licensees authorized to use strontium-90 eye applicators
96-63	Potential Safety Issue Regarding the Shipment of Fissile Material	12/05/96	All U.S. Nuclear Regulatory Commission licensees authorized to possess special nuclear material in unsealed quantities greater than a critical mass
96-57	Incident-Reporting Requirements Involving Intakes, During a 24-Hour Period that May Cause a Total Effective Dose Equivalent in Excess of 0.05 Sv (5 rem)	10/30/96	All U.S. Nuclear Regulatory Commission licensees
96-54	Vulnerability of Stainless Steel to Corrosion When Sensitized	10/17/96	All material licensees
96-53	Retrofit to Amersham 660 Posilock Radiography Camera to Correct Inconsistency in 10 CFR Part 34 Compatibility	10/15/96	All industrial radiography licensees
96-52	Cracked Insertion Rods on Troxler Model 3400 Series Portable Moisture Density Gauges	09/26/96	All U.S. Nuclear Regulatory Commission portable gauge licensees and vendors

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Information Notice No.	Subject	Date of Issuance	Issued to
96-71	Licensee Response to Indications of Tampering, Vandalism, or Malicious Mischief	12/27/96	All holders of OLs or CPs for nuclear power reactors
96-70	Year 2000 Effect on Computer System Software	12/24/96	All U.S. Nuclear Regulatory Commission licensees, certificate holders, and registrants
96-69	Operator Actions Affecting Reactivity	12/20/96	All holders of OLs or CPs for nuclear power reactors
96-68	Incorrect Effective Diaphragm Area Values in Vendor Manual Result in Potential Failure of Pneumatic Diaphragm Actuators	12/19/96	All holders of OLs or CPs for nuclear power reactors
96-67	Vulnerability of Emergency Diesel Generators to Fuel Oil/Lubricating Oil Incompatibility	12/19/96	All holders of OLs or CPs for nuclear power reactors
96-66	Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators	12/13/96	All U.S. Nuclear Regulatory Commission Medical Use Licensees authorized to use strontium-90 (Sr-90) eye applicators

OL = Operating License
CP = Construction Permit

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Original Signed by *J. Combs*
 Donald A. Cool, Director
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

Technical Contact: Robert L. Ayres, NMSS
 (301) 415-5746
 E-mail: rxa1@nrc.gov

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* See previous concurrence
 ** Coordinated with FDA

OFC	IMAB	IMAB	IMAB	IMOB		
NAME	Rayres <i>for</i>	*SMerchant	*LWCamper	*JPiccone		
DATE	12/22/96	12/17/96	12/17/96	12/18/96		
OFC	TechEd	DD/IMNS	D/IMNS			
NAME	*EKrause	FCCombs	*DACool			
DATE	12/11/96	12/17/96	12/18/96			

C=COVER E=COVER\ENCLOSURE N=NO COPY OFFICIAL RECORD COPY: G:\TELETER.IN

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NAME	Rayres <i>ADA</i>		*SMerchant	*LWCamper	<i>JJPiccone</i>
DATE	12/16/96		12/17/96	12/17/96	12/18/96
OFC	TechEd		DD/IMNS	D/IMNS	
NAME	*EKrause		FCCombs	DACool	
DATE	12/11/96		12/ /96	12/18/96	

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