NMSS

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NRCB 92-02

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

August 24, 1992

NRC BULLETIN 92-02: SAFETY CONCERNS RELATING TO "END OF LIFE" OF AGING THERATRONICS TELETHERAPY UNITS

92 SEP -8 A7:37

Addressees

For Action - All Teletherapy Licensees

For Information - None

Purpose

This bulletin: (1) notifies you about concerns related to the useful safe life of older Theratronics International Limited (formerly AECL Medical) teletherapy units; (2) requests that all action addressees take the appropriate recommended actions; and (3) requires that all action addressees provide the U.S. Nuclear Regulatory Commission with a report describing their findings and actions taken and notify NRC when they have completed all actions associated with this bulletin.

Description of Circumstances

Beginning with the discovery of crack(s) in the cast iron arms of a Theratron 80 (T80) teletherapy unit in 1983, Theratronics has issued three "User Bulletins" to all consignees of Theratron 60's (T60's) and T80's. These bulletins all addressed the necessity of inspecting the arms in accordance with a revised maintenance section of the unit's instruction manual.

In 1991, the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) became concerned about this possible safety issue and inspected Theratronics, concentrating primarily on the cobalt therapy devices. In addition to the problem with the cracked arms, the FDA inspection found that the firm had other continuing problems with the T60 and T80 units. These problems include gantry rotation and timer malfunctions, stuck sources, optical distance indicator errors, problems with bolts, pins, and screws, and inadvertent raising of the patient couch without switch activation.

As a result of the problems uncovered during FDA inspections, Theratronics voluntarily issued a user bulletin that was classified as a "Safety Alert" by FDA in May 1991 (FDA # M-020/021-1). This bulletin advised all T60 and T80 users of the potential for cracking in the arms of their units. In addition, as the result of the inspections Theratronics subsequently issued a number of user bulletins affecting various firm products that were classified as "Recalls" by FDA. FDA has also placed in effect an "Import Alert" preventing the importation of all of the firm's radiation therapy treatment and planning

9208180147 PDR I&E Bulletin 92-002 920824
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systems from Canada. The latter action will remain in effect until the company satisfies the FDA that the problems uncovered in the FDA's inspection of the firm are corrected.

After these actions, Theratronics issued two "User Bulletins" -- CUB-91-03NA, dated June 5, 1991, and CUB-91-04NA, dated June 24, 1991 (Attachments 1 and 2). The purpose of these bulletins was to inform users of the firm's Theratron Junior, Eldorado A, Eldorado G, Eldorado Super G, Ceasatron E, Eldorado 6 and Eldorado 8 (CUB-91-03NA) and users of its Theratron 60 and 80 (CUB-91-04NA) teletherapy units that, in the opinion of the manufacturer, these units have exceeded their useful safe life and should be removed from service, especially those units with cast iron components. The manufacturer also stated that spare parts were becoming increasingly difficult to provide and, in some cases, were completely unavailable. As of the issue date of the respective bulletins, the manufacturer further stated that routine service, service contracts, replacement sources, and accessories would no longer be made available. Further, spare parts would only be supplied on an "as available" basis.

Discussion

The potential hazard to patients and employees from crushing injuries due to catastrophic failure of the arm is obvious. In 1987, a mechanical failure in the drive unit of an aging Eldorado 6 unit resulted in a crushing fatality to a patient. Such failures could also expose, or leave exposed, the source. In such an event, significant exposures to the patient and/or employees could readily occur, particularly if the failure rendered inoperable the normal emergency source-retraction mechanisms. A worst-case scenario -- an injured individual trapped in the treatment room with an exposed source -- could lead to a fatal overexposure.

The broader safety issues related to the withdrawal of the manufacturer's support for these units concern NRC. This lack of support may lead to incidents of deferred or improper maintenance at a time when service and maintenance requirements are normally increasing as components age. Improper servicing, repair, or substitution of spare parts could readily produce device failures resulting in overexposures to both patients and employees.

The Theratronics International Limited teletherapy models affected by the manufacturer's withdrawal of support are:

Theratron Junior
Eldorado A
Eldorado G
Eldorado Super G
Ceasatron E
Eldorado 6
Eldorado 8
Theratron 60
Theratron 80 and 80R

In addition, the Theratron 60 and 80 models are subject to cracks developing in the cast iron arm.

Requested Actions

Those addressees possessing one or more of the affected models must submit the information specified under "Reporting Requirements" within 60 days after receipt of this bulletin. Those addressees who do not have one of the listed models need only submit an abbreviated report listing the make(s) and model(s) they possess, along with a statement that, based on make(s) and/or model(s), they are exempt from the additional reporting requirements of this bulletin.

Reporting Requirements

Provide information on how you are going to handle the "end-of-useful-life" issue and the maintenance and servicing issues related to the manufacturer's withdrawal of support. At a minimum, the following information should be included in your report:

(1) Make and model number of teletherapy unit

(2) Date of manufacture (if known)

(3) Serial number

(4) Describe the present use of your teletherapy unit, (e.g., research, instrument calibration, routine clinical use, backup for an accelerator, etc). If used for patient treatment, what is the average weekly patient workload and what alternative(s) are available to treat these patients if the unit had to be removed from service for an extended period of time for service or replacement?

(5) If you possess one of the T60 or T80 units with a cast iron arm, describe your commitment to perform the special inspections per Theratronic's revised Survey and Inspection Procedure I 1024 G091G10 REV C. and your action(s) if stress cracking is discovered.

(6) What has been the service record of your teletherapy units for the past five years? List each failure, its cause, length of down time, and replacement components, if any, necessary to return the unit to service.

(7) Is your teletherapy unit presently covered by a service contract and, if so, by whom? What is the expiration date of the contract? Do you expect to renew the contract and, if so, for what additional period of time? What is covered by the contract?

(8) Describe your facility's commitment to ensure the continued safe clinical use of these aging teletherapy units. At a minimum, you should address the following concerns:

(a) Inspections

(i) Frequency
(ii) What will be inspected?
(iii) Who will perform the inspections?
(iv) Operational checks

(b) Service

(i) Prearranged or on an "as-required" basis?
(ii) If prearranged, specify by agreement or service contract
(iii) Who will perform the service?

(c) Parts replacement

(i) How necessary replacement parts will be obtained
(ii) How suitability of any replacement parts (equal or better) will be determined

(d) Service, source exchange and 5-year inspections

(i) Identify the name of the organization(s) that will perform these services and specify the firm's NRC or Agreement State license number
(ii) If you have no organization identified to perform these services, then what are your plans at source-exchange time and/or 5-year inspection.

(e) For any needed repairs or essential inspections for which necessary resources are unavailable or delayed, you must commit to halting all use of the unit until the necessary repairs and/or inspection have been accomplished.

Address the required written reports to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, under oath or affirmation, under the provisions of Section 182a, Atomic Energy Act of 1954, as amended. In addition, submit a copy to the appropriate regional administrator.

This request is covered by Office of Management and Budget Clearance Number 3150-0017, which expires February 28, 1993. The estimated average number of burden hours is 20 person-hours per licensee response, including those needed to assess the new recommendations, search data sources, gather and analyze the data, and prepare the required letters. (This estimate of the average number of burden-hours pertains only to the identified response-related matters and does not include the time needed to implement the requested action.) Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch, Division of Information Support Services, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to the Paperwork Reduction Project

(3150-0017), Office of Information and Regulatory Affairs, NEOB-3019, Office of Management and Budget, Washington, D.C. 20503.

Although no specific request or requirement is intended, the following information would be helpful to NRC in evaluating the cost of complying with this bulletin:

(1) The licensee staff's time and costs to perform requested inspections, corrective actions, and associated testing

(2) The licensee staff's time and costs to prepare the requested reports and documentation

(3) The additional short-term costs incurred as a result of the inspection findings such, as the costs of the corrective actions or the costs of down time

(4) An estimate of the additional long-term costs that will be incurred in the future as a result of implementing commitments such as the estimated costs of conducting future inspections or increased maintenance

If you have any questions about this matter, please contact the technical contact listed below or the appropriate regional office.

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

Technical contact: Robert L. Ayres, IMAB
301-504-3423

Attachments:
1. CUB-91-03NA
2. CUB-91-04NA
3. List of Recently Issued NMSS Bulletins
4. List of Recently Issued NRC Bulletins

Attachments filed in Jackets

THERATRONICS

CUB-91-03NA

USER BULLETIN

DATE: JUNE 5, 1991

SUBJECT: USEFUL SAFE LIFE NOTICE

UNITS: USERS OF THERATRON JUNIOR, ELDORADO A, ELDORADO G, ELDORADO SUPER G, CEASATRON E, ELDORADO 6 AND ELDORADO 8

The Theratron Junior, Eldorado A, Eldorado G, Super G and the Ceasatron E units have not been manufactured for the last 29 years and some units are now up to 35 years old. The Eldorado 6 and 8 units have not been manufactured for the last 18 years and some of these units are now almost 30 years old. The units are showing signs of wear and tear, and spare parts are becoming increasingly difficult to provide and in some cases not available at all.

Users of the older models were notified in 1982 and 1987 that the units had exceeded their useful life and should be retired from service. Notwithstanding these notices, a number of units are still in service.

Theratronics believes it is our duty to inform you again, in our opinion as manufacturer, these units have exceeded their useful safe life and should be removed from service.

To support this view, we feel we can no longer responsibly offer routine billed service, service contracts, replacement sources or accessories for these old units. Further, spare parts shall only be supplied on an as available basis.

As a responsible manufacturer, which has stood behind its product line for the past forty (40) years, we wish to continue to assist our customers. Therefore, a Representative of Theratronics shall contact you in the near future to discuss the limitations of these units in more detail and the options available to suit your individual needs.

Enclosed is a self-addressed acknowledgement card. Please complete and return the acknowledgement card upon receipt of this bulletin.

Meanwhile, should you have any questions, please contact Mr. Phil Cowan, our Cobalt Specialist, at Phone 1-800 T-COBALT or Fax 214-416-4101.

Theratronics International Limited

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THERATRONICS

CUB-91-04NA

USER BULLETIN

DATE: JUNE 24, 1991

SUBJECT: USEFUL SAFE LIFE NOTICE

UNITS: THERATRON 60 AND 80 USERS

The Theratron 60 and 80 cobalt therapy units have not been manufactured for the last 18 years and some are now up to 28 years old. The units are showing signs of wear and tear, and spare parts are becoming increasingly difficult to provide.

Theratronics believes it is our duty to inform you that, in our opinion as manufacturer, these units have exceeded their useful safe life and should be removed from service, especially those with cast iron components.

As noted in the User Bulletin CUB-90-7 issued October 24, 1990 a crack developed in a cast iron arm on a Theratron 80. The user ceased use of the unit and had it removed from service. In addition, recently a crack was found in a cast iron beamstopper, the cause has not yet been established.

In light of these circumstances, we feel we can no longer responsibly offer routine billed service, service contracts, replacement sources or accessories for these old units. Further, spare parts shall only be supplied on an as available basis.

As a responsible manufacturer, which has stood behind its product line for the past forty (40) years, we wish to continue to assist our customers. Therefore, a Representative of Theratronics shall contact you in the near future to discuss the limitations of these units in more detail and the options available to suit your individual needs.

Enclosed is a self-addressed acknowledgement card, questionnaire and a revised Survey and Inspection Procedure I 1024 G09/G10 REV. C for cast iron components. Please ensure that your cast iron components are inspected as soon as possible and in accordance with the applicable manual.

Return the acknowledgement card and completed questionnaire upon receipt of this bulletin and the appropriate copy of the Survey and Inspection Procedure upon completion of the inspection.

Meanwhile, should you have any questions, please contact Mr. Phil Cowan, our Cobalt Specialist, at 1-800-T-COBALT or Fax 1-214-416-4101.

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LIST OF RECENTLY ISSUED NMSS BULLETINS

Bulletin No.	Subject	Date of Issuance	Issued to
91-01	Reporting Loss of Criticality Safety Controls	10/18/91	All fuel cycle and uranium fuel research and development licensees.
88-06	Actions to be Taken for the Transportation of Model No. SPEC 2-T Radiographic Exposure Device	06/14/88	All NRC licensees authorized to manufacture, distribute, or operate radiographic exposure devices or source changers.

LIST OF RECENTLY ISSUED NRC BULLETINS

Bulletin No.	Subject	Date of Issuance	Issued to
92-01	Failure of Thermo-Lag 330 Fire Barrier System to Maintain Cabling in Wide Cable Trays and Small Conduits Free from Fire Damage	06/24/92	All holders of OLs or CPs for nuclear power reactors.
91-01	Reporting Loss of Criticality Safety Controls	10/18/91	All fuel cycle and uranium fuel research and development licensees.
89-01, Supp. 2	Failure of Westinghouse Steam Generator Tube Mechanical Plugs	06/28/91	All holders of OLs or CPs for PWRs.
89-01, Supp. 1	Failure of Westinghouse Steam Generator Tube Mechanical Plugs	11/14/90	All holders of OLs or CPs for PWRs.
90-02	Loss of Thermal Margin Caused by Channel Box Bow	03/20/90	All holders of OLs or CPs for BWRs.
90-01	Loss of Fill-Oil in Transmitters Manufactured by Rosemount	03/09/90	All holders of OLs or CPs for nuclear power reactors.
89-03	Potential Loss of Required Shutdown Margin During Refueling Operations	11/21/89	All holders of OLs or CPs for PWRs.
88-10, Supp. 1	Nonconforming Molded-Case Circuit Breakers	08/03/89	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit