

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

December 8, 1992

NRC BULLETIN 92-03: RELEASE OF PATIENTS AFTER BRACHYTHERAPY

Addressees: (see attached list)

'93 JAN -7 P2:13

For Action - Brachytherapy Licensees Authorized to use the Omnitron Model 2000 High Dose Rate (HDR) Afterloading Brachytherapy Unit

For Information - None

Purpose

This Bulletin: (1) notifies addressees about the risk related to the release of brachytherapy patients without positive assurance that all of the implant material has been removed prior to the patient's release; (2) requests that all addressees take the actions specified below; and (3) requires that all addressees provide the U.S. Nuclear Regulatory Commission with a report stating whether the requested actions have been taken or whether use of the Omnitron Model 2000 High Dose Rate Unit has been discontinued.

Description of circumstances

According to preliminary information received by the Nuclear Regulatory Commission, an outpatient being treated with an Omnitron Model 2000 Unit at the Indiana, Pennsylvania Regional Cancer Center of Oncology Services Corporation was returned to a nearby nursing home after treatment with the source remaining in the patient's body. The treatment took place on November 16, 1992, and the patient died on November 21, 1992. Based on the patient's medical records, the preliminary conclusion of NRC's consultant physician is that the patient either died as a result of exposure to radiation, or that radiation exposure was a major contributor to her death. Until the source, approximately 4 curies of Iridium-192, was removed from the nursing home after the patient's death, it subjected nursing home residents and staff, as well as visitors, to radiation exposure. Radiation doses to these members of the public are still being evaluated.

Cancer Center personnel experienced difficulty with source placement in one of the patient's five treatment catheters. Subsequent investigation after the patient's death found that a short piece of the cable containing the iridium source had broken off and remained in the catheter. Although a wall-mounted area monitor alarmed when the treatment was completed, the licensee's staff believed the device was emitting a false signal and chose to ignore it. Also, no survey of the patient was conducted utilizing a hand-held survey

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per S Fridley on  
6/11/93

instrument to determine if a source remained in the patient as required by 10 CFR 35.404(a).

A second incident was reported on December 7, 1992. A source again separated from the drive cable on a Omnitron Model 2000 Unit during brachytherapy treatment of a patient at the Greater Pittsburgh Cancer Center of Oncology Services Corporation, Pittsburgh, PA. In this instance, the source separation was detected at the end of the treatment and recovery of the source was made.

#### Discussion and Requested Actions

The NRC and the United States Food and Drug Administration (FDA) are conducting ongoing investigations of the cause of the failure associated with the Omnitron Model 2000 Unit. Until the failure analysis information is available, it is unclear whether the manufacturer will be required to recall the device, implement design modifications and/or conduct field retrofits to prevent the recurrence of the problem. Consequently, all patient treatments given using this manufacturer's system must be viewed as having a risk of similar failure. Therefore, licensees are requested to either discontinue using the Omnitron 2000 Unit or immediately implement the following actions in conjunction with any use of the unit:

1. In accordance with 10 CFR 35.404(a), the licensee shall make a radiation survey of the patient with an appropriate radiation detection survey instrument to confirm that all sources have been removed. This survey is in addition to any indication of radiation levels provided by an area radiation monitor. The surveys shall be done immediately after completion of the therapy procedure prior to removal of the patient from the shielded HDR treatment room, and appropriately documented with initials/signatures.
2. A licensee shall not conduct any procedure for which a decoupled source cannot be removed expeditiously from the patient and placed in a shielded condition. The licensee shall have written emergency procedures describing actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. The licensee shall assure that appropriate staff and equipment are available immediately, at the location that the HDR procedure is performed, to implement the written emergency procedures. Equipment should include shielded storage containers, remote handling tools, and, if appropriate, supplies to help surgically remove sources from the patient to include scissors and cable cutters. The emergency source removal procedure should minimize exposure to healthcare personnel while maximizing safety to the patient.
3. The licensee shall ensure that personnel are trained in both the routine use of the device and emergency procedures to return the source to a safe condition. Training shall be provided immediately for new personnel and retraining provided semiannually for all personnel. The licensee shall retain the records of this training for a period of three years.

### Reporting Requirements

All addressees are required to report, in writing, within 15 days of the date of this Bulletin whether the actions described in this Bulletin have been taken or whether the use of the Omnitron Model 2000 device has been discontinued.

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, of the Atomic Energy Act of 1954, as amended. In addition, submit a copy to the appropriate NRC Regional Administrator.

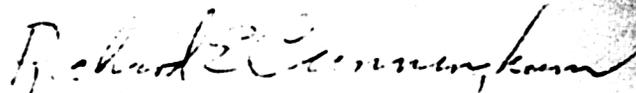
The request is covered by Office of Management and Budget Clearance Number 3150-0012, which expires June 30, 1994. The estimated average number of burden hours is 20 person-hours per licensee response to this Bulletin. (This estimate of the average number of burden-hours pertains only to the preparation of the required report and does not include implementation of the requested actions). 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 Office of Information and Regulatory Affairs, (3150-0012) NEOB-3019, Office of Management and Budget, Washington, DC 20503.

Licensees should also be aware of the user facility reporting requirement of the Safe Medical Devices Amendments of 1990. A user may be required to submit a report to FDA if a medical device causes or contributes to a death. In addition, the user may be required to report to the manufacturer any serious injury or illness involving the device. For information on user facility reporting requirements or to determine if they apply to your operation contact Bryan Benesch, FDA, at (301) 427-1144.

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 comply with the requests in this Bulletin;
- (2) The licensee staff's time and costs to prepare the requested report and documentation; and
- (3) An estimate of the additional long-term costs that will be incurred in the future as a result of implementing commitments.

If you have any questions regarding this matter, please contact the technical contact listed below or the appropriate NRC Regional Office.



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