PDR for John Ratte

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

December 17, 1992

NRC INFORMATION NOTICE 92-84: RELEASE OF PATIENTS TREATED WITH TEMPORARY IMPLANTS

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Addressees

All Nuclear Regulatory Commission Medical Licensees.

Purpose

The purpose of this notice is to inform licensees about concerns about releasing brachytherapy patients without positive assurance that all implant material (sources) have been removed from patients before their release. These concerns encompass all brachytherapy procedures, including both manual and remote afterloading techniques, using temporary implants. 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 new NRC requirements; therefore, no specific action or written response is required.

Description of Circumstances

According to preliminary information that the Nuclear Regulatory Commission received, an outpatient, being treated with an Omnitron Model 2000 High Dose Rate (HDR) Afterloading Brachytherapy treatment system, at a freestanding cancer center, was returned to a nearby nursing home, after treatment, with the source remaining in the patient's body. The treatment took place November 16, 1992; the patient died 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. He noted that the symptoms and timing of the symptoms were consistent with severe, acute radiation syndrome. 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. This catheter was removed and the patient returned to the nursing home, with the remaining four catheters in place. 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 one of the catheters. 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

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Updated on 7/28/97

patient was conducted, using a hand-held survey 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, and lodged in the catheter, external to the patient. In this instance, the physicist detected the source separation during the treatment; he cut the catheter behind the source and immediately removed the patient from the treatment room. The remaining portion of the catheter was then removed from the patient and both the catheter and patient were scanned with a survey instrument, to confirm that no part of the source remained within either the catheter or patient.

Additionally, failure to perform proper radiation surveys, after treatment of the patients with low-dose manual brachytherapy procedures, has led to loss of control of one or more sources. NRC has received several recent reports of such incidents, where the sources were eventually discovered in normal trash, at a disposal facility.

Discussion

The NRC and the U. S. Food and Drug Administration are conducting ongoing investigations of the cause of the failures associated with the Omnitron Model 2000 Unit. Until 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 using this manufacturer's system must be viewed as having a high risk for similar failures. Although NRC has no recent reports of similar failures of other HDR models, such failures are possible. Because of the severe consequence of the loss of control of one of these high-activity sources, users of all HDRs need to be especially vigilant, in all of their operations, to minimize the effects of any machine or procedural errors that could lead to loss of control of the source.

Preliminary information, from the NRC investigation team at the cancer center site involved in the November 16, 1992 incident, is that the room monitor often produced false alarm indications; thus licensee personnel considered it to be unreliable. It would appear that licensee personnel had been conditioned, by repetitive false alarms, to ignore any information provided by this primary radiation safety device. This device was used in place of a portable radiation survey instrument, needed to conduct surveys required by 10 CFR 35.404(a).

Based on what is presently known about this incident, it is clear that if proper radiation surveys of the patient had been made, before releasing the patient from the facility, the consequences of this incident would have been largely avoided. Although rare, the loss of control of one or more of these high-activity radiation sources has great potential for causing injury or death to patients, workers, and members of the public. Thus, because the

consequences of such a loss of control are so severe, NRC, through this information notice, is alerting all medical licensees and expects them to consider all reasonable measures to minimize the possibility of such an event ever occurring again.

All licensees are reminded that, in accordance with 10 CFR 35.404(a), the licensee shall perform a radiation survey of all patients being treated with brachytherapy sources, with an appropriate radiation detection or measurement survey instrument, as specified in 10 CFR 35.420, to confirm that all sources have been removed. For surveys associated with HDR procedures, the licensee needs to use a portable radiation measurement survey instrument, capable of measuring dose rates of 1 millirem per hour to at least 1000 millirem per hour. It is important to use survey instruments with appropriate sensitivity, since the high exposure rates associated with these sources can easily saturate survey instruments, resulting in a false negative reading. This survey is in addition to any indication of radiation levels provided by an area radiation monitor. An area monitor provides an immediate indication of a possible problem and thus serves a useful function as an early warning device. However, it has neither the accuracy nor sensitivity required to comply with the survey requirements of 10 CFR 35.404(a). The surveys shall be performed immediately after completion of the therapy procedure before removal of the patient from the treatment room, and appropriately documented in accordance with 10 CFR 35.404(b).

It is expected that licensees will carefully consider the risks associated with any procedure for which a decoupled source cannot be removed expeditiously, from the patient, and placed in a shielded condition. NRC Bulletin 92-03, dated December 8, 1992, requested all Omnitron HDR licensees to 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. This would include providing for the necessary staff and equipment to be immediately available, 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 (including scissors and cable cutters) to help surgically remove sources from the patient. The emergency source-removal procedure should minimize exposure to health-care personnel, while maximizing safety to the patient.

The licensee should train personnel in both the routine use of brachytherapy sources and devices and emergency procedures to return sources to a safe shielded condition. This training should include emergency procedures and dry runs, for coupled and decoupled sources that either remain in the patient or remain exposed external to the patient. Licensees are also reminded of the general requirements, such as those contained in 10 CFR Part 19, 10 CFR 35.410, and license conditions, to have personnel trained to perform assigned tasks in a manner that assures radiation safety. Training should be provided immediately for new personnel, and retraining provided semiannually, for all personnel. The records of this training should be maintained for a period of three years.

This information notice requires no specific action or written response. If you have any questions about the information provided, 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
and Safeguards

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

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

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LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
92-72	Employee Training and Shipper Registration Requirements for Transporting Radioactive Materials	10/18/92	All U.S. Nuclear Regulatory Commission licensees.
92-62	Emergency Response Information Requirements for Radioactive Material Shipments	08/24/92	All U.S. Nuclear Regulatory Commission licensees.
92-58	Uranium Hexafluoride Cylinders - Deviations in Coupling Welds	08/12/92	All fuel Cycle Licensees.
92-38	Implementation Date for the Revision to the EPA Manual of Protective Action Guides and Protective Actions for Nuclear Incidents	05/12/92	All holders of OLs or CPs for nuclear power reactors, non-power reactors and materials licensees authorized to possess large quantities of radioactive material.
92-37	Implementation of the Deliberate Misconduct Rule	05/08/92	All Nuclear Regulatory Commission Licensees.
92-34	New Exposure Limits for Airborne Uranium and Thorium	05/06/92	All licensees whose operations can cause airborne concentrations of uranium and thorium.
92-14	Uranium Oxide Fires at Fuel Cycle Facilities	02/21/92	All fuel cycle and uranium fuel research and development licensees.
92-11	Soil and Water Contamination at Fuel Cycle Facilities	02/05/92	All uranium fuel fabrication and conversion facilities.

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
88-23, Supp. 4	Potential for Gas Binding of High-Pressure Safety Injection Pumps during A Design Basis Accident	12/18/92	All holders of OLs or CPs for nuclear power reactors.
92-83	Thrust Limits for Limitorque Actuators and Potential Overstressing of Motor-Operated Valves	12/17/92	All holders of OLs or CPs for nuclear power reactors.
92-82	Results of Thermo-Lag 330-1 Combustibility Testing	12/15/92	All holders of OLs or CPs for nuclear power reactors.
92-81	Potential Deficiency of Electrical Cables with Bonded Hypalon Jackets	12/11/92	All holders of OLs or CPs for nuclear power reactors.
92-80	Results of Thermo-Lag 330-1 Combustibility Testing	12/07/92	All holders of OLs or CPs for nuclear power reactors.
92-79	Non-Power Reactor Emergency Event Response	12/01/92	All holders of OLs or CPs for test and research reactors.
92-78	Piston to Cylinder Liner Tin Smearing on Cooper-Bessemer KSV Diesel Engines	11/30/92	All holders of OLs or CPs for nuclear power reactors.
92-77	Questionable Selection and Review to Determine Suitability of Electropneumatic Relays for Certain Applications	11/17/92	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit