UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

November 24, 2003

NRC INFORMATION NOTICE 2003-21: HIGH-DOSE-RATE-REMOTE-AFTERLOADER EQUIPMENT FAILURE

Addressees:

All medical licensees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees of a recently reported medical event that occurred during the conduct of a high-dose-rate-remote-afterloader (HDR) brachytherapy procedure. The medical event involved error in selection of ancillary equipment--transfer tube--required for use of the HDR unit, resulting in failure of the sealed source to reach its intended position for treatment, and failure of the sealed source to retract on completion of the procedure.

It is expected that recipients will review this information for applicability to their licensed operations and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

An Agreement State licensee reported that a 170.2 gigabecquerel (4.6 curie) iridium-192 sealed source contained in a Nucletron MicroSelectron HDR afterloader device--Model Number 31324--failed to retract on completion of a patient treatment. The physicist entered the treatment room and attempted to manually retract the sealed source, which was stuck in the transfer tube, the source conveyor device between the HDR unit and the applicator used for the procedure. Manual retraction of the sealed source failed. The physician entered the treatment room, disconnected the apparatus from the patient, and dropped the transfer tube into a lead container. Both the physicist and physician then moved the patient out of the room. The physicist observed that 2 minutes had elapsed since he entered the treatment room. The physicist surveyed the patient with a radiation detection instrument to confirm that the source had been removed. The physicist then re-entered the room to perform a radiation survey. He confirmed that the source was within the transfer tube and that it was shielded by the lead container. The physicist measured 0.1 millisievert (mSv)/hr at 0.91 meters [10 millirem (mrem)/hr at 3 feet] from the shielded container. The room was locked and posted until the

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manufacturer's representative arrived. The manufacturer's representative also was unable to retract the source from the transfer tube into the HDR unit. He then disconnected the transfer tube from the HDR unit, placed the transfer tube, containing the sealed source, into a shipping container, and arranged for returned of the transfer tube to the manufacturer, for further investigation.

Doses to the patient, physicist, and physician (as originally reported) were estimated as follows: (1) patient's skin dose, at 10 centimeters (cm) [3.9 inches (in.)] from the sealed source, was 0.61 sieverts (Sv) (61 rem); (2) physicist's whole-body dose (deep-dose equivalent), for the 2-minute exposure, was 0.45 mSv (45 mrem); (3) physician's whole-body dose (deep-dose equivalent) was 1.25 mSv (125 mrem), and extremity dose was 0.15 Sv (15 rem).

The Agreement State and NRC are continuing to investigate this event. Because of the importance to licensees of the information contained in this IN, it is being issued before completion of the investigation of this event.

Discussion:

Although the transfer tube used was manufactured by Nucletron for use with the Nucletron MicroSelectron HDR afterloader device, it was a rigid gynecological-type tube, not designed for use with the Proxima Therapeutics Mammosite applicator being used by the licensee for the procedure being performed. Nucletron indicated that the licensee should have used its flexible transfer tube, approved for use for non-gynecological-type treatments, which is designed to accommodate the Mammosite applicator.

As a result of the incorrect choice of transfer tube (i.e., an incorrect transfer tube being used with the Mammosite applicator) during the procedure, the sealed source was inadvertently positioned inside the transfer tube at a distance of 10-14 cm (3.9-5.5 in.) from the patient's breast, not in the breast, as planned. That is, the source of the radiation never arrived at the intended treatment site within the patient's body. Also, the use of the incorrect Nucletron transfer tube for the Mammosite applicator apparently caused the subsequent failure of the source to retract.

Licensees performing HDR brachytherapy procedures are expected to review this IN and:

- Assure that ancillary devices to be used with an HDR brachytherapy unit for a therapeutic procedure are designed for use with, or are known to be compatible with, both the HDR afterloader unit and with any applicator(s) to be used during the procedure;

- Assure that all HDR afterloader brachytherapy unit users are familiar with the operating procedures and applicable usage restrictions of all equipment to be employed in a procedure before actual use of such devices and ancillary equipment;

- Encourage device and equipment users to review all of the vendors' pertinent documentation and to clarify any concerns with the vendors, regarding particular devices, before using the devices for patient treatments. If, based on prior review of a

vendor's documentation, and possibly discussion with a vendor, a user considers that directions provided by an on-site vendor's representative may perhaps be in error, licensees are expected to clarify any such discrepancies with the manufacturer before use of the device(s); and

- Promptly report all system malfunctions to the vendors, and if required, to the licensing authorities.

This IN requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact below, or the appropriate regional office.

/RA/

Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Ronald E. Zelac, Ph.D., NMSS
301-415-7635
e-mail: rez@nrc.gov

Attachments:
1. List of recently issued NMSS Information Notices
2. List of recently issued NRC Information Notices

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2003-20	Derating Whiting Cranes Purchased Before 1980	10/22/2003	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; applicable decommissioning reactors, fuel facilities, and independent spent fuel storage installations.
2003-16	Icing Conditions Between Bottom of Dry Storage System and Storage Pad	10/06/2003	All 10 CFR Part 72 licensees and certificate holders.
2003-12	Problems Involved in Monitoring Dose to the Hands Resulting from the Handling of Radiopharmaceuticals	08/22/2003	All holders of 10 CFR Parts 32, 33, and 35 licenses.
2003-10	Criticality Monitoring System Degradation at BWX Technologies, Inc., Nuclear Products Division, Lynchburg, VA	08/04/2003	All U.S. Nuclear Regulatory Commission (NRC) licensees authorized to possess a critical mass of special nuclear material.
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OL = Operating License
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2003-19	Unanalyzed Condition of Reactor Coolant Pump Seal Leakoff Line During Postulated Fire Scenarios or Station Blackout	10/06/2003	All holders of operating licenses or construction permits for pressurized water reactors (PWRs).
2003-18	General Electric Type SBM Control Switches With Defective Cam Followers	09/26/2003	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2003-17	Reduced Service Life of Automatic Switch Company (ASCO) Solenoid Valves With Buna-N Material	09/29/2003	All holders of operating licenses for nuclear power reactors.
2003-16	Icing Conditions Between Bottom of Dry Storage System and Storage Pad	10/06/2003	All 10 CFR Part 72 licensees and certificate holders.

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