

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

August 15, 1997

NRC INFORMATION NOTICE 97-65: FAILURES OF HIGH-DOSE-RATE (HDR)
REMOTE AFTERLOADING DEVICE SOURCE
GUIDE TUBES, CATHETERS, AND
APPLICATORS

Addressees

All high-dose-rate (HDR) remote afterloader licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to reports of failures in source guide tubes, catheters, and applicators used with HDR devices supplied by the three major U. S. vendors of these devices. Licensees should be aware of the potential for similar failures during the course of patient treatments and the possible risk(s) associated with the loss of containment of a HDR source. 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

During the last several years, NRC has received reports of failures of HDR source guide tubes, catheters, and applicators used to place and contain the HDR source during patient treatments. Most recently, the Food and Drug Administration (FDA) provided NRC with its inspection findings documenting such failures for Nucletron Corporation devices. A brief summary of the known failures follows:

1. The FDA's March 1997, inspection findings at Nucletron Corporation included reported failures of Ring I/U tube applicators, Flexiguide cone catheters breaking inside patients, problems with numbers wearing off transfer tubes, catheter length variations, and one reported problem with an esophageal catheter.
2. A similar FDA inspection of Omnitron Corporation, in November 1993, found numerous reported failures with their Flexineedle applicators, and GYN and standard catheters. Reports indicate that components of the Flexineedle applicators have separated inside patients and, in some cases, have not been retrieved.

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3. In 1993, an NRC licensee reported that a Gamma Med II source guide tube broke away from a vaginal cylinder. This resulted in the HDR source being driven onto the table, rather than into the vaginal cylinder. A subsequent check for defects by the licensee of all guide tubes and applicators, revealed that six bronchial, one tandem, and two intracavity tubes were defective.

The causes for these defects in the applicators, guide tubes, and catheters have been variously ascribed to design defects, errors in manufacturing, or improper sterilization procedures. While actions on the part of manufacturers have likely resulted in correction of most of the identified problems, licensees performing HDR brachytherapy treatments should be aware of the potential for failure of HDR device accessories.

Discussion

Given that HDR device applicators, guide tubes, and catheters can fail suddenly and in an unexpected manner, it is important that users of these components take appropriate precautions, to the extent practicable, to protect their patients from injuries. NRC is particularly concerned about the possibility of both patients and health care providers receiving significant radiation exposures. The potential for significant radiation exposure could be reduced if licensees were aware of the possibility of such failures and, as a direct result, were prepared to safely and expeditiously handle the resulting emergency situation.

In recognition of the hazards associated with an event where a HDR source either becomes stuck or detached during a patient treatment, NRC requested, in NRC Bulletin 93-01, that licensees commit to providing written emergency procedures for responding to either of these potential emergency situations. This item was subsequently incorporated in Policy and Guidance Directive FC 86-4 (Rev. 1) which provided NRC license reviewers with guidance for licensing HDR device applications. Some licensees responded to this request by stating that such an event is improbable, since the source is always contained within the guide tube and/or applicator of the device, thus, negating any need for establishing the requested emergency procedures. Knowing that there have been multiple reported failures of this containment system, licensees may wish to reconsider the necessity of having preplanned emergency surgical procedures as an integral part of their emergency response procedures for HDR patient treatments.

Although the probability of a failure of the containment system simultaneous to the source sticking or becoming detached would be expected to be very small, the failure of a containment system could, for example, increase the probability that the HDR source would become stuck or detached by obstructing the path of the source, or a HDR source that became stuck or detached within the source transport/containment system could stress the containment system, resulting in breaching the containment. Thus, a failure of either the containment system or the source could easily increase the probability for the failure of the other.

The FDA has the primary responsibility for regulating the design and manufacture of these HDR guide tubes, applicators, and catheters. Therefore, it is important that the FDA be notified of any failures or defects with such devices, so that any problems, with a potential for patient injury, can be corrected.

Licensees should 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.

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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. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

*Attachment filed in
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LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
97-64	Potential Problems Associated with Loss of Electrical Power in Certain Teletherapy Units	08/13/97	All U.S. Nuclear Regulatory Commission medical teletherapy licensees
97-61	U.S. Department of Health and Human Services Letter, to Medical and manufacturers/distributors, on the Year 2000 Problem	08/06/97 Device Manu-	All U.S. Nuclear Regulatory Commission medical licensees, veterinarians, butors of medical devices
97-58	Mechanical Integrity of In-Situ Leach Injection Wells and Piping	07/31/97	Holders of and Applicants for Licenses for In-Situ Leach Facilities
97-57	Leak Testing of Packaging Used in the Transport of Radioactive Material	07/30/97	Suppliers and users of packaging for the transportation of radioactive material required to perform packaging leak tests
97-56	Possession Limits for Special Nuclear Material at the Envirocare of Utah Low-Level Radioactive Waste Disposal Facility	07/28/97	All licensees authorized to possess special nuclear material
97-55	Calculation of Surface Activity for Contaminated Equipment and Materials	07/23/97	All Uranium Recovery Licensees

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97-63	Status of NRC Staff's Review of BWRVIP-05	08/07/97	All holders of OLs or CPs for boiling water reactors
97-62	Unrecognized Reactivity Addition During Plant Shutdown	08/06/97	All holders of OLs or CPs for nuclear power reactors
97-61	U.S. Department of Health and Human Services Letter, to Medical Device Manu- facturers, on the Year 2000 Problem	08/06/97	All U.S. Nuclear Regulatory Commission medical licensees, veterinarians, and manu- facturers/distributors of medical devices
97-60	Incorrect Unreviewed Safety Question Deter- mination Related to Emergency Core Cooling System Swapover from the Injection Mode to the Recirculation Mode	08/01/97	All holders of OLs or CPs for pressurized-water reactors
97-59	Fire Endurance Test Results of Versawrap Fire Barriers	08/01/97	All holders of OLs or CPs for nuclear power reactors

OL = Operating License
CP = Construction Permit

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OFFICE	IMAB*	E	IMAB*	E	IMAB*	E	IMOB*	OGC* no legal objection
NAME	RAyres		CHaney		LWCamper		JPiccone	STreby
DATE	6/30/97		7/1/97		7/1/97		8/7/97	7/29/97
OFFICE	TechEd*		DD:IMNS		D:IMNS			
NAME	EKraus		FCombs		DCool			
DATE	6/12/97		6/12/97		6/12/97			

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DATE	6/30/97		7/1/97		7/1/97		8/7/97	7/29/97
OFC	TechEd**		DD/IMNS		D/IMNS			
NAME	EKraus		<i>[Signature]</i> FCCombs		<i>[Signature]</i> DACsett			
DATE	6/12/97		8/1/97		8/8/97			

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DATE	6/30/97		7/1/97	<i>[Signature]</i> 7/1/97		7/1/97		<i>7/28/97</i>

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