



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

(FSME-09-076, September, Other, IN 2009-15)

September 4, 2009

ALL AGREEMENT STATES, MICHIGAN, NEW JERSEY

ISSUANCE OF NRC INFORMATION NOTICE 2009-15 (FSME-09-076)

Purpose: To notify the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) has issued Information Notice (IN) 2009-15, Varian Medical Systems Varisource High Dose-Rate Remote Afterloader Events: Source Retraction Problems. The IN is addressed to all NRC medical use licensees authorized to possess or use a Varian Medical Systems Varisource High Dose Rate Remote Afterloader (VariSource HDR), and all Radiation Control Program Directors and State Liaison Officers.

Background: The NRC is issuing IN 2009-15, Varian Medical Systems Varisource High Dose-Rate Remote Afterloader Events: Source Retraction Problems, to: 1) alert addressees about recently reported events where service engineers experienced problems with the VariSource HDR during source retractions, and 2) have recipients review the information to avoid similar problems.

Discussion: IN 2009-15, Varian Medical Systems Varisource High Dose-Rate Remote Afterloader Events: Source Retraction Problems is provided to the Agreement States to inform licensees of the precautions they may take to reduce the risk of problems occurring. The IN can be found at:

<http://adamswebsearch2.nrc.gov/idmws/ViewDocByAccession.asp?AccessionNumber=ML092120085>

NRC Point of Contact: If you have any questions on this correspondence, please contact me at 301-415-3340 or the individual named below.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, DC 20555

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NRC INFORMATION NOTICE 2009-15: VARIAN MEDICAL SYSTEMS VARISOURCE
HIGH DOSE-RATE REMOTE AFTERLOADER
EVENTS: SOURCE RETRACTION PROBLEMS

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC master materials licensees authorized to possess or use a Varian Medical Systems VariSource High Dose Rate Remote Afterloader (VariSource HDR). All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice to alert addressees about recently reported events at three different locations where service engineers experienced problems with the VariSource HDR during source retractions. During all of the incidents, the source wire became stuck outside of the afterloader and required the Varian personnel to use the manual-retract handle to return the source to a safe-shielded position. The NRC expects recipients to review the information for applicability to their facilities and to consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, neither specific action nor written response is required.

The NRC is providing this information notice to the Agreement States for their information and for distribution to their medical use licensees, as appropriate.

DESCRIPTION OF CIRCUMSTANCES

The NRC received an event report involving VariSource HDR devices at three separate facilities where service personnel using standard procedures were unable to retract the source into the shielded tungsten safe, following source replacement. This event report, required in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 21, "Reporting of Defects and Noncompliance," involved three separate cases that occurred between December 2, 2008, and December 30, 2008. In all cases, the service personnel had completed a source exchange and were in the process of conducting positional verification testing of the new source. During the testing, the source wire failed to return to the shielded tungsten safe, requiring the service personnel to implement the emergency procedures. The service personnel first attempted to retrieve the source by depressing various emergency buttons located on the HDR device and device console. When this proved unsuccessful, the

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service personnel turned the manual-retract handle on the HDR device and successfully returned the source to the tungsten shield.

Preliminary data suggest that the restrictions on the movement of the source wire occurred internally within the HDR, caused by buildup of material within one of the components along the source wire path. Specifically, in two cases, service personnel reported the presence of compacted black dust in the source guide fixtures near the source drive. None of the incidents occurred during patient treatment; however, the possibility of this happening in the future cannot be ruled out.

DISCUSSION

All of the incidents occurred because of an accumulation of dust buildup in the source wire path. It has been determined that the buildup is composed of dust materials produced from normal wear within the device. Analysis of the dust particles has shown that the dust is composed of the same material as the nickel titanium source wire. However, an analysis of the affected source wires, conducted by visual and mechanical examination, has shown that the integrity of the wires was not compromised in any of these events.

This information notice reminds licensees to be aware of the potential problem associated with the accumulation of dust in these devices, leading to source wire constrictions. As a result of the problems caused by the buildup, Varian implemented special maintenance procedures, including the routine cleaning of any components exhibiting dust buildup on a regular basis. Initially, Varian service personnel conducted this cleaning at every source exchange; as the buildup rate of dust has become known, Varian has increased the frequency accordingly.

Varian has released information regarding these events to its customers in Customer Technical Bulletin CTB-VS-640A. The bulletin reminds customers to review their emergency procedures in the event that the source wire must be retracted using the manual-retract handle. The bulletin also asks that customers immediately report any errors that occur upon active wire retraction with error code 1A, class 2, "Active wire drive slippage....," which may indicate that the HDR is trending toward an internal path constriction.

Furthermore, licensees should be aware of the following:

- A user-resettable error code of 1A, class 2, "Active wire slippage..." should be reported to the manufacturer, Varian, immediately.
- To shield the source, personnel would need to implement emergency procedures, which may require turning the manual-retract handle.
- The VariSource HDR is approved for use with an 11-curie iridium-192 source. With such a source the exposure rate is 20.7 rem per hour at 50 centimeters. The exposure rate from an unshielded 10-curie iridium-192 source is 18.8 rem per hour at 50 centimeters (as referenced in the Varian VS2000 SSD).
- After an event where the source has become stuck outside of the afterloader, patient treatments should not resume until repairs are complete.

CONTACTS

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.

Robert Lewis, Director */RA/*
Division of Materials Safety
and State Agreements
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Enclosure:
List of Recently Issued FSME
Generic Communications

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
03/30/09	IN-2009-07	Withholding of Proprietary Information from Public Disclosure	All current holders of and potential applicants for licenses, certificates of compliance, permits, or standard design certifications, as well as any other persons submitting a request that information be withheld from public disclosure under the provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Section 2.390, "Public inspections, exemptions, requests for withholding.
07/27/09	IN-2009-12	Exempt Distribution Licensing Requirements For Irradiated Gemstones	All holders of NRC exempt distribution licenses authorized to distribute irradiated gemstones. Organizations associated with importing, distributing or selling irradiated gemstones or jewelry containing irradiated gemstones. All Radiation Control Program Directors and State Liaison Officers.
07/29/09	IN-2003-22, Supplement 1	Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC master material licensees; all Agreement State Radiation Control Program Directors and State Liaison Officers.
04/29/09	RIS-2009-05	Uranium Recovery Policy Regarding: (1) The Process for Scheduling Licensing Reviews of Applications for New Uranium Recovery Facilities and (2) The Restoration of Groundwater at Licensed Uranium In-Situ Recovery Facilities	All holders of operating licenses for uranium recovery facilities and all companies who have submitted applications to construct new uranium recovery facilities of all types (conventional mills, heap leach operations, and in-situ recovery facilities) or letters of intent to submit such applications.
05/07/09	RIS-2009-07	Status Update for the Implementation of NRC Regulatory Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material	All U.S. Nuclear Regulatory Commission material and fuel cycle licensees. All Radiation Control Program Directors and State Liaison Officers.
07/13/09	RIS-2009-09	Use Of Multiple Dosimetry and Compartment Factors in Determining Effective Dose Equivalent from External Radiation Exposures	All U.S. Nuclear Regulatory Commission licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.
<p>Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</p>			