

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

October 17, 2007

NRC INFORMATION NOTICE 2007-35:     VARIAN MEDICAL SYSTEMS  
  VARISOURCE HDR EVENTS:  
  IRIDIUM-192 SOURCE PULLED FROM  
  SHIELDED POSITION

**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 (IN) to alert addressees to recently reported events where the use of the emergency manual retract hand wheel on the VariSource HDR has caused the active iridium-192 (Ir-192) source to be pulled out of the shielded position. 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 IN are not new NRC requirements; therefore, no specific action or written response is required.

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

**DESCRIPTION OF CIRCUMSTANCES**

NRC has received four event reports in the last three years, two of them recently, involving the VariSource HDR Ir-192 source having been pulled out of the shielded position, while using the manual retract hand wheel. The four events occurred in a range of different situations, two occurred during clinical use of the afterloader, one occurred during routine QA/QC checks, and the other occurred during student training. In one of the four incidents reported, while the patient treatment was being planned, the wire containing the dummy (non-radioactive) source did not return during pre-treatment preparations. The manual retract hand wheel, which is intended only for the wire containing the radioactive source and not for the dummy source, was used by the

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physicist in an attempt to retract the dummy source. However, when the physicist turned the hand wheel, the active source was pulled out of the tungsten safe. Two of the events occurred when the operator of the VariSource HDR attempted to retract a “stuck” dummy source with the manual retract hand wheel. Their attempt to manually retract the dummy source caused the active Ir-192 source to be pulled out of the tungsten safe. The remaining event occurred during a training exercise when an instructor asked four students to simulate using the manual retract hand wheel, however, two of the students actually turned the hand wheel and caused the active Ir-192 source to be pulled out of the tungsten safe.

## **DISCUSSION**

Three of the four events occurred because the operators used the manual retract hand wheel in an attempt to retract the dummy source back into the VariSource HDR unit. The fourth event occurred during a training session. The warning label on the manual retract hand wheel reads “Warning – Active Source Wire Emergency Retract only. Turn the hand wheel for a maximum of 12 turns or until the radiation alarm ceases. Contact Varian Service.” Varian filed an initial notification dated September 17, 2007, with NRC in accordance with 10 CFR 21.21, following the latest event on July 15, 2007. The report delineated the event and the design characteristics of the VariSource HDR unit for safe use.

While potential long-term solutions are being considered, licensees should be aware that consequences of the active Ir-192 source being pulled out of the tungsten safe would result in the following:

1. The source would be contained within the unit, but would be unshielded and could not be returned to the shielded position.
2. The exposure rate for a 10 Curie Ir-192 source that has been pulled out of the tungsten safe would have an exposure rate of 18 R/hr at 50 cm.
3. A recovery operation would be needed to retrieve and secure the source.
4. Treatments could not resume until a new source wire is installed.

This IN serves as a reminder that the manual retract hand wheel on the VariSource HDR units is intended only for the wire containing the Ir-192 source. The manual retract hand wheel does not retract the dummy source. In the event that the dummy source is stuck in the out position, the console displays Error Code 88. The operators should consult the operator’s manual provided by Varian Medical Systems and contact Varian Service. Licensees should also read Varian’s Customer Technical Bulletin (CTB) VS-366A, “Clarification on the Use of the Emergency Retract Hand Wheel to Prevent Accidental Exposure”. The CTB is available at the following website:

[www.varian.com/shared/oncy/pdf/CTB-VS-366a.pdf](http://www.varian.com/shared/oncy/pdf/CTB-VS-366a.pdf)

In addition, in the event of an emergency where an operator needs to use the manual retract hand wheel to return the active Ir-192 source to the shielded position, operators should be aware that the number of turns necessary to return the source to the tungsten safe may vary. The number of turns may vary depending on how extended the source is initially and on any potential for slippage between the pinch rollers and the source wire, especially with a freshly lubricated source wire. The VariSource HDR units are designed

in such a manner that the operator only knows if the source has returned to the shielded position when the audible radiation alarms and red light indicator turn off. Operators should be aware that if the manual retract hand wheel is turned too many times the active Ir-192 source can be pulled out of the tungsten safe. The unit was not designed to have a positive lock to prevent the source from being pulled out of the tungsten safe or to indicate that the source is in the shielded position.

## **CONTACT**

This IN requires no specific action of written response. If you have any questions about this IN, please contact one of the individuals listed below or the appropriate regional office.

***/RA/***

Janet R. Schlueter, Director  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Technical Contact: Tomas Herrera, FSME  
(301) 415-7138  
E-mail: [txh1@nrc.gov](mailto:txh1@nrc.gov)

Medical Issues Contact: Cindy Flannery, FSME  
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Enclosure: List of Recently Issued FSME/NMSS Generic Communications

Note: NRC generic communications may be found on the NRC public Website, <http://www.nrc.gov>, under Electronic Reading Room/Document Collections.

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<b>OFC</b>	DMSSA/SSSB	DMSSA/SSSB	DMSSA/MSEA	DMSSA/SSSB
<b>NAME</b>	THerrera:tyh	JJankovich	SWastler for CFlannery	CEinberg
<b>DATE</b>	10/02/07	10/02/07	10/04/07	10/09/07
<b>OFC</b>	DMSSA/MSEA	FSME/DMSSA	FSME/DMSSA	
<b>NAME</b>	AMcIntosh	RLewis	JSchlueter	
<b>DATE</b>	10/09/07	10/17/07	10/17/07	

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<b>Recently Issued FSME/NMSS Generic Communications</b>			
Date	GC No.	Subject	Addressees
02/02/07	IN-07-03	Reportable Medical Events Involving Patients Receiving Dosages of Sodium Iodide Iodine-131 less than the Prescribed Dosage Because of Capsules Remaining in Vials after Administration	All U.S. Nuclear Regulatory Commission medical use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
02/28/07	IN-07-08	Potential Vulnerabilities of Time-reliant Computer-based Systems Due to Change in Daylight Saving Time Dates	All U. S. Nuclear Regulatory Commission licensees and all Agreement State Radiation Control Program Directors and State Liaison Officers.
03/13/07	IN-07-10	Yttrium-90 Theraspheres <sup>®</sup> and Sirspheres <sup>®</sup> Impurities	All U.S. Nuclear Regulatory Commission (NRC) Medical Licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
04/04/07	IN-07-13	Use of As-Found Conditions to Evaluate Criticality-related Process Upsets at Fuel Cycle Facilities	All licensees authorized to possess a critical mass of special nuclear material.
05/02/07	IN-07-16	Common Violations of the Increased Controls Requirements and Related Guidance Documents	All licensees who are implementing the U.S. Nuclear Regulatory Commission (NRC) Order Imposing Increased Controls (EA-05-090), issued November 14, 2005 and December 22, 2005.
05/21/07	IN-07-19	Fire Protection Equipment Recalls and Counterfeit Notices	All holders of operating licenses for nuclear power reactors and fuel cycle facilities; except those licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel; and except those licensees for decommissioned fuel cycle facilities.
06/11/07	IN-07-20	Use of Blank Ammunition	All power reactors, Category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants.

Date	GC No.	Subject	Addressees
07/19/07	IN-07-25	Suggestions from the Advisory Committee on the Medical Use of Isotopes For Consideration to Improve Compliance With Sodium Iodide I-131 Written Directive Requirements in 10 CFR 35.40 and Supervision Requirements in 10 CFR 35.27	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
08/08/07	IN-07-23	Inadvertent Discharge of Halon 1301 Fire-suppression System from Incorrect and/or Out-of-date Procedures	All holders of operating licenses for nuclear power reactors, except those who have permanently ended operations and have certified that fuel has been permanently removed from the reactor vessel. All holders of licenses for fuel cycle facilities.
08/13/07	IN-07-26	Combustibility of Epoxy Floor Coatings at Commercial Nuclear Power Plants	All holders of operating licenses for nuclear power reactors and fuel cycle facilities except licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel.
09/13/07	IN-07-30	Radiological Controls Create Criticality Safety Accident Scenario for Fissile Solution Container Transport at Fuel Cycle Facility	All licensees authorized to possess a critical mass of special nuclear material.
09/28/07	IN-07-33	Exposures To Members Of The Public Caused By Inadequate Controls Over Well Logging Sources	All U.S. Nuclear Regulatory Commission Well Logging Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
03/01/07	RIS-07-03	Ionizing Radiation Warning Symbol	All U.S. Nuclear Regulatory Commission licensees and certificate holders. All Radiation Control Program Directors and State Liaison Officers
03/09/07	RIS-07-04	Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission	All holders of operating licenses for nuclear power reactors and holders of and applicants for certificates for reactor designs. All licensees, certificate holders, applicants, and other entities subject to regulation by the U.S. Nuclear Regulatory Commission of the use of source, byproduct, and special nuclear material
03/20/07	RIS-07-05	Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally-occurring and Accelerator-produced Radioactive Material	All NRC materials licensees, Radiation Control Program Directors, State Liaison Officers, and NRC's Advisory Committee on the Medical Uses of Isotopes
04/05/07	RIS-07-07	Clarification of Increased Controls for Licensees That Possess Collocated Radioactive Material During Transportation Activities	All U.S. Nuclear Regulatory Commission (NRC) licensees issued NRC's Order Imposing Increased Controls and all Radiation Control Program Directors and State Liaison Officers

Date	GC No.	Subject	Addressees
05/04/07	RIS-07-09	Examples of Recurring Requests for Additional Information (RAIs) for 10 CFR Part 71 and 72 Applications	All holders of, and applicants for, a: (1) 10 CFR Part 71 certificate of compliance (CoC) for a radioactive material transportation package; (2) 10 CFR Part 72 CoC for a spent fuel storage cask; and (3) 10 CFR Part 72 specific license for an independent spent fuel storage installation (ISFSI).
06/27/07	RIS-06-27, Suppl. 1	Availability of NRC 313A Series of Forms and Guidance for Their Completion	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers.
05/15/07	RIS-07-10	Subscriptions To New List Server For Automatic Notifications Of Medical-Related Generic Communications, <i>Federal Register</i> Notices And Newsletters	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers.
08/31/07	RIS-07-13	Verification of the Authenticity of Materials Possession Licenses	All U.S. Nuclear Regulatory Commission materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
09/07/07	RIS-07-18	Data for Updating the Interim Inventory of Radioactive Sources	All U.S. Nuclear Regulatory Commission (NRC) Part 40, Part 50, Part 70, Part 72, and Part 76 licensees and certificate holders who are authorized to possess sources of radioactive material at the Category "3.5" (as defined below) activity or higher.
10/04/07	RIS-07-23	Date For Operation Of National Source Tracking System	All licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials. All Radiation Control Program Directors and State Liaison Officers.

Note: A full listing of generic communications may be viewed at the NRC public website at the following address:  
<http://www.nrc.gov/Electronic Reading Room/Document Collections/Generic Communications>