Part 21 (PAR) Event # 46758

Rep Org: VARIAN MEDICAL SYSTEMS		**Notification Date / Time:** 04/15/2011 15:12	(EDT)
Supplier: VARIAN MEDICAL SYSTEMS		**Event Date / Time:** 03/23/2011	(EST)
		Last Modification: 04/15/2011	
Region:		**Docket #:**	
City:		**Agreement State:** No	
County:		**License #:**	
State:			
NRC Notified by: RICHARD G. PICCOLO		**Notifications:** KATHLEEN O'DONOHUE	R2DO
HQ Ops Officer: HOWIE CROUCH		PART 21 - FSME	
Emergency Class: NON EMERGENCY			
10 CFR Section:			
21.21 UNSPECIFIED PARAGRAPH			

POTENTIAL DEFECT IDENTIFIED IN A VARIAN MEDICAL SYSTEMS HIGH DOSE RATE AFTERLOADER

On March 23, 2011, a technician was installing a VariSource High Dose Rate (HDR) Afterloader - Model VariSource IX when the active wire composed of a 10 Ci Ir-192 source failed to extend. After troubleshooting it was discovered that the wire was stuck on the wedge block which is part of the emergency retract mechanism. (See NRC Event Notice 46695)

Engineering evaluation by the vendor, Varian Medical Systems, Inc., has identified a very small amount of material in the wedge block which has a small bore that the source wire passes through. Otherwise, nothing remarkable was identified.

This machine is a new unit with a very low number of source extensions. There is no history of similar events with new units of this type.

The vendor has issued a Tech Tip for all new sites and is investigating a new design for the wedge block with a goal of implementing any new design by April 30, 2012. Additionally, all VariSource HDR customers have received a copy of Customer Technical Bulletin CTB-VS-640A that discusses the potential of source wire path constriction and source wire jamming.

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IE20
NMSS

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-----Fax Notification-----

April 15, 2011

NRC Operations Center
Fax: 301.816.5151
Phone: 301.816.5100

Initial Notification for 10 CFR 21 report filing – Event 46695

Varian Medical Systems, Inc. is submitting this correspondence based on an event involving a high dose rate afterloader at one hospital site on March 23, 2011. The NRC Operations Center was called on March 24, 2011 in accordance with 10 CFR 30.50(b)(2).

This fax contains preliminary information subject to revision. A final written report in accordance with 10 CFR 21.21 (d)(4) will be sent to the NRC Operations Center and the NRC Regional Director within 30 days of the event date.

Please contact me at (office) 434.951.8675, or (mobile) 434.242.3314 as needed.

Very truly yours,

Richard G. Piccolo

Richard G. Piccolo, CHP
Varian Brachytherapy RSO

Part 21 Fax – Grady Memorial Hospital VSiX

Fax notification in accordance with 10 CFR 21.21 (d)(3)(ii) and § 21.21 (d)(4)
Event 46695

1. Name and address of the individual or individuals informing the Commission.

Richard G. Piccolo
Varian Medical Systems, Inc.
700 Harris Street, Ste. 109
Charlottesville VA 22903

2. Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

VariSource HDR Afterloader – Model VariSource iX

3. Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

The VariSource HDR Afterloader is manufactured by:

Varian Medical Systems, Inc.
Gatwick Road
Crawley, West Sussex RH102RG
United Kingdom

4. Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

The active source wire may jam in the wedge block and cause the source to become stuck outside of the unit's tungsten shield.

This is the first time this event has occurred in a new unit.

The event involving the new unit has occurred only at Grady Memorial Hospital, 80 Jesse Hill Drive SE, Atlanta GA 30303. No other sites have been involved.

Engineering evaluation has determined the following:

a. An very small amount of material was found in a source guide fixture known as the wedge block. The source wire passes through a small bore in this fixture.

b. The nickel-titanium source wire involved in this incident was manufactured from stock material that has been in use for many months.

c. There have been no known changes to the production workflow that would account for this event.

d. The integrity of the source wire did not appear compromised in this event. Microscopic examination of the wire did not disclose anything that would have contributed to the wire jam.

e. The HDR unit properly parked the source in the tungsten safe without the use of the emergency retract handle.

Safety hazard – unintended radiation exposure from the source being outside the tungsten shield.

- total collective dose equivalent from the event: 2 mrem (electronic dosimeter)

5. The date on which the information of such defect or failure to comply was obtained.

The event occurred on March 23, 2011. Varian's RSO called the NRC Operations Center on the following day after the source was safely recovered. During a subsequent telephone on Monday April 11, 2011 the NRC advised that a Part 21 filing would be appropriate due to the involvement of the wedge block.

6. In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

This is the first time a source wire has become jammed in a new unit with a very low number of source extensions – likely around 10-15.

Therefore, there are no units similarly affected and we have not seen any other similar events with new units in the history of this device.

7. The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

Short term corrective action

Tech Tip TT-VS-1247C, which was issued as part of the response to Event 47744 will be applied at all new sites prior to loading the active source wire.

Long term corrective action

A new design for the wedge block is being investigated and will be implemented when finalized. The new wedge block will replace the current design in the production of new VariSource HDR units in Crawley England.

Length of time that will be taken to complete the action – After the design is determined it will take several months of testing to ensure it is a valid design change. Varian has a goal of April 30, 2012 for completing this design and its implementation in new production units. This goal is dependent on achieving a valid design and may change based on our test results.

8. Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

All VariSource HDR customers have received a copy of a Customer Technical Bulletin CTB-VS-640A that discusses the potential of source wire path constriction and source wire jamming.

9. In the case of an early site permit, the entities to whom an early site permit was transferred.

Not applicable