Hospital Event # 44774

Rep Org:	VARIAN MEDICAL SYSTEMS	**Notification Date / Time:**	01/14/2009 16:38 (EST)
Licensee:	VARIAN MEDICAL SYSTEMS	**Event Date / Time:**	01/14/2009 (EST)
		Last Modification:	01/14/2009
Region:	1	**Docket #:**	
City:	CHARLOTTESVILLE	**Agreement State:**	No
County:		**License #:**	
State:	VA		

NRC Notified by:	RICHARD G. PICCOLO	**Notifications:**	ART BURRITT	R1
HQ Ops Officer:	JASON KOZAL		STEVEN RUDISAIL	R2
Emergency Class:	NON EMERGENCY		DAVE PASSEHL	R3
10 CFR Section:			RYAN LANTZ	R4
21.21	UNSPECIFIED PARAGRAPH		ANDREA KOCK	FSME
			JOHN JANKOVICH EMAIL	

PART 21 REPORT DUE POTENTIAL ISSUE OF AFTERLOADER SOURCE STICKING

"The active source may have movement difficulties and become stuck during source extension or retraction. The problem may occur with the source outside of the HDR unit's tungsten shield.

"This type of event was first seen in December 2008.

"This event has occurred three times:

"a) Southwest Regional Cancer Center, Austin TX - December 2, 2008

"b) Hershey Medical Center, Hershey PA - December 11, 2008

"c) Stanford University Medical Center, Stanford, CA - December 30, 2008

"In each case the problem occurred during a routine source exchange and patients were not involved. The emergency retract handle was used in each occurrence to retract the source and park it safely in the HDR unit's tungsten shield. The relationship between the source exchange and the problem is unknown."

"The affected sites in the United States are as follows:"

St. Joseph's - Mercy Hospital of Macomb - Clinton Twp., MI

Cancer Healthcare Associates Cedars Med Ctr - Miami, FL

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NMSS

Hospital Event # 44774

Providence Hospital - Anchorage, AK

Coborn Cancer Center - St. Cloud, MN

Stanford University Medical Center - Palo Alto, CA

Barnes Jewish #2 - Washington University - St. Louis, MO

Mayo Clinic - Rochester, MN

DeKalb Medical Center - Decatur, GA

Cy-Fair Cancer Center - Houston, TX

Billings Clinic - Billings, MT

Palm Beach Cancer Institute - West Palm Beach, FL

St. Lukes - Bethlehem, PA

University of Nebraska Medical Center - Omaha, NE

Geisinger Health System - Wilkes-Barre, PA

Southwest Regional Cancer Center - Austin, TX

Hershey Medical Center - Hershey, PA

Carolinas Medical Center - Charlotte, NC

Cheyenne Regional Medical Center - Cheyenne, WY

Mary Washington Hospital - Fredericksburg, VA

Treasure Coast Radiation Oncology - Stuart, FL

Mayhill Denton Cancer Center - Denton, TX

Hamilton Medical Center - Dalton, GA

Providence Hospital - Everett, WA

Good Samaritan Hospital - Downers Grove, IL

Seattle Cancer Care Alliance - Seattle, WA

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--- FACSIMILE NOTIFICATION---

January 14, 2009

NRC Operations Center
FAX – (301) 816-5151
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Initial Notification for 10 CFR 21 report filing

Varian Medical Systems, Inc. is submitting this correspondence based on the potential applicability of 10 CFR 21 to an event involving a High Dose Rate Afterloader at three hospital sites in December 2008.

This facsimile correspondence complies with 10 CFR 21.21 (d)(3)(i) and contains preliminary information subject to revision or clarification. A final written report in accordance with 10 CFR 21.21 (d)(4) will be sent to the NRC Operations Center and the NRC Region II Regional Director within 30 days.

Please contact me at (434) 951-8675, or email <rick.piccolo@varian.com.

Very truly yours,

Richard G. Piccolo

Richard G. Piccolo, CHP
Varian Brachytherapy RSO

The following responses are provided in accordance with 10 CFR 21.21(d)(4)

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 22902

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 models 200 and iX bounded by serial numbers 430 through 505.

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 may have movement difficulties and become stuck during source extension or retraction. The problem may occur with the source outside of the HDR unit's tungsten shield.

This type of event was first seen in December 2008.

This event has occurred three times:

a) Southwest Regional Cancer Center, Austin TX - December 2, 2008

b) Hershey Medical Center, Hershey PA – December 11, 2008

c) Stanford University Medical Center, Stanford, CA – December 30, 2008

In each case the problem occurred during a routine source exchange and patients were not involved. The emergency retract handle was used in each occurrence to retract the source and park it safely in the HDR unit's tungsten shield. The relationship between the source exchange and the problem is unknown.

Engineering evaluation has determined the following:

i) A compacted fine black dust was found in two source guide fixtures near the source drive. The source wire passes through a small bore in these fixtures. In one fixture the bore is 0.2 mm greater than the diameter of the source wire. The dust is composed of materials that are used in source wire production and a solid lubricant used during a source exchange – therefore, finding these materials showed that an unexpected contaminant was not present as far as we could determine. The compacted material breaks up immediately if it is tapped, and is not hard in that sense of the word. However, in these three cases it appears that the dust is responsible in preventing the wires from automatically retracting properly.

ii) The source wires at the three sites were made from the inventory of stock source wire material that has been in use since February 2007 as dummy wires, and September 2007 as source wires. Therefore, there have been tens of thousands of source extensions using the same stock of source wire without seeing similar events.

iii) There have been no deliberate changes to the production workflow that would account for these events.

iv) The emergency source retract hand crank operated as designed.

Safety hazard – unintended radiation exposure from the source being outside the tungsten shield. Personnel exposures from the three events are as follows:

i) total collective dose equivalent from 3 events – 499 mrem
ii) highest individual dose equivalent – 269 mrem

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

The first event occurred on December 2, 2008

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

The investigation has been narrowed to units bound by serial numbers 430 through 505. Affected sites in the United States are given in the following table.

St. Joseph's - Mercy Hospital of Macomb - Clinton Twp. MI	VS 430	15855 19 Mile Road	Clinton Twp	MI	48038
Cancer Healthcare Associates Cedars Med Ctr	VS 431	1321 NW 14th Street	Miami	FL	33136

Providence Hospital (Anchorage AK)	VS 432	3200 Providence Drive	Anchorage	AK	99519
Coborn Cancer Center - St. Cloud, MN	VS 433	1900 CentraCare Circle, Suite 1600	St. Cloud	MN	56303
Stanford University Medical Center	VS 435	820 Quarry Road	Palo Alto	CA	94304
Barnes Jewish #2 - Washington University	VS 436	724 S Euclid Room 0005	St. Louis	MO	63110
Mayo Clinic - Rochester	VS 437	321 Third Ave SW	Rochester	MN	55905
DeKalb Medical Center	VS 439	2675 N Decatur Road, Suite G03	Decatur	GA	30033
Cy-Fair Cancer Center - Houston	VS 440	10650 Steepletop Drive	Houston	TX	77065
Billings Clinic	VS 441	2800 10th Ave North	Billings	MT	59107
Palm Beach Cancer Institute	VS 442	1309 North Flagler Drive	West Palm Beach	FL	33401
St. Luke's	VS 444	240 Centronia Rd	Bethlehem	PA	
University of Nebraska Medical Center	VS 445	4367 Emile Street	Omaha	NE	68198
Geisinger Health System VS 200 to iX	VS 446	1000 East Mountain Drive	Wilkes-Barre	PA	18711
Southwest Regional Cancer Center	VS 447	901 W 38th Street	Austin	TX	78705
Hershey Medical Center	VS 448	500 University Drive	Hershey	PA	17033
Carolinas Medical Center	VS 450	1000 Blythe Blvd	Charlotte	NC	28203
Cheyenne Regional Medical Center	VS 452	214 East 23rd St	Cheyenne	WY	82001
Mary Washington Hospital	VS 453	1001 Sam Perry Blvd	Fredericksburg	VA	22401
Treasure Coast Radiation Oncology	VS 455	2107 SE Ocean Boulevard	Stuart	FL	34996
Mayhill Denton Cancer Center	VS 457	3537 South I-35 East, Suite 111	Denton	TX	76210
Hamilton Medical Center - Dalton GA	VS 460	Judd Cancer Trmt Cntr, 1200 Memorial Dr	Dalton	GA	30722
Providence Hospital - Everett WA	VS 500	1717 13th St	Everett	WA	98201
Good Samaritan Hospital (Downers Grove IL)	VS 503	3815 Highland Ave	Downers Grove	IL	60515
Seattle Cancer Care Alliance	VS 501	825 Eastlake Ave	Seattle	WA	98109

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.

Corrective action – On December 23, 2008 a new maintenance instruction was issued to the Field Service Representatives. The instruction provides directions on the specific parts of the HDR unit in which the jams have occurred and how to inspect and clean them.

The maintenance is to be carried out during the next planned or unplanned visit by the Varian Field Service Representative.

Responsible organization – Varian Brachytherapy is the responsible organization within Varian Medical Systems, Inc.

Length of time that will be taken to complete the action – The maintenance will be ongoing at each site. The root cause has not been determined and the frequency for continuing maintenance will be determined after more information is gathered and analyzed.

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.

- Preventive maintenance has been implemented at suspected facilities.
- Facilities using the VariSource HDR unit have not been notified.
- Advice to customers is being considered.