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titled Initial Notification for 10 CFR 21 Report Filing

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--- FACSIMILE NOTIFICATION---

January 14, 2009

NRC Operations Center
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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:

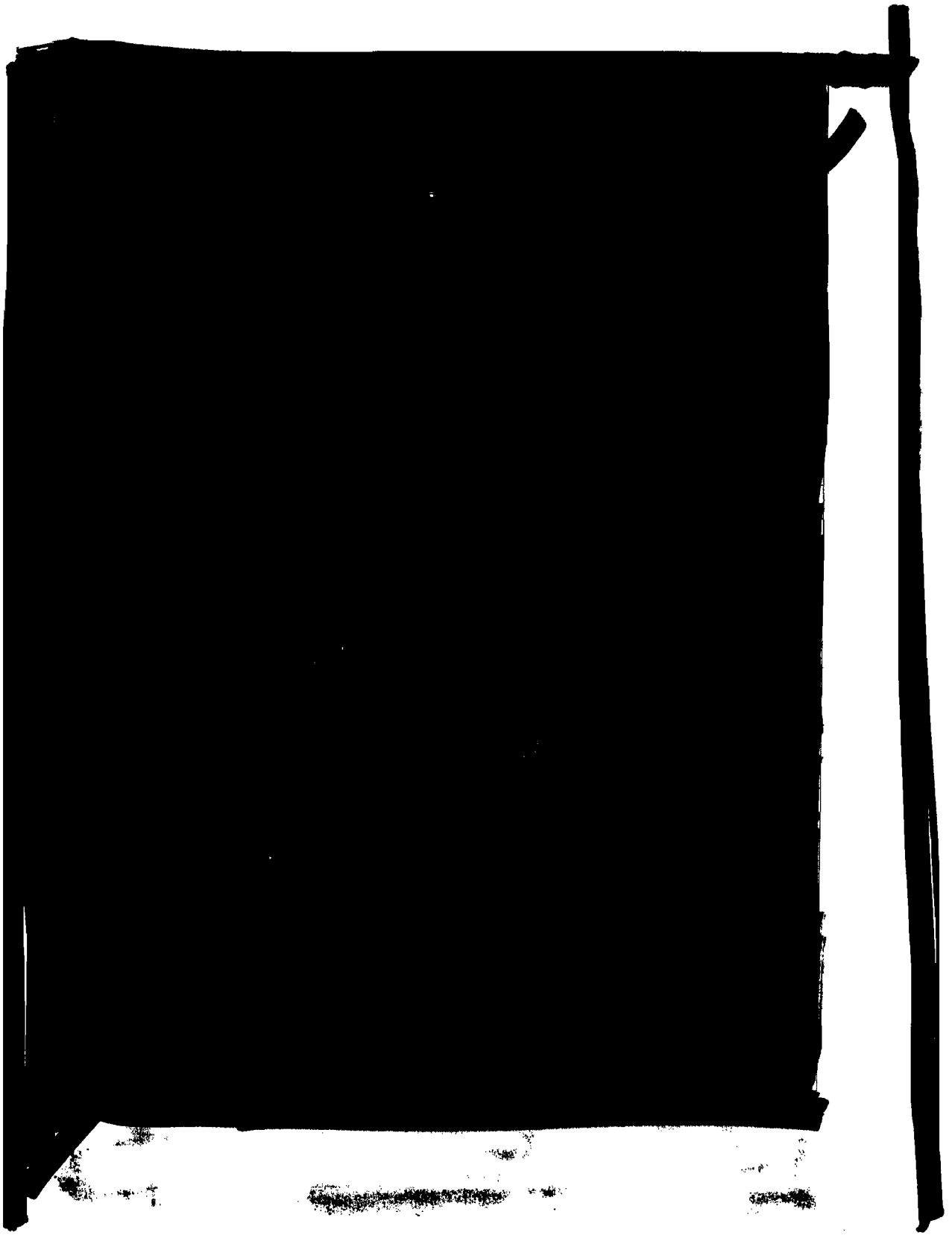
i) total collective dose equivalent from 3 events – 499 mrem
ii) highest individual dose equivalent – 269 mrem

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.



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.