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ML092080150 Letter dated 7/23/2009

Varian Medical Systems, Inc., Event 44774

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Document Control Desk
US Nuclear Regulatory Commission
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Re: Varian Medical Systems, Inc., Event 44774

Varian Medical Systems, Inc. is submitting this additional information related to Event 44774. This correspondence is company confidential.

Very truly yours,

Richard G. Piccolo, CHP
Varian Brachytherapy RSO

cc: Regional Administrator
USNRC Region I
475 Allentown Road
King of Prussia, PA 19406

Report No. 3 to the NRC related to VariSource jammed source wire event.

NRC Event 44774

This report is provided to state the root cause of the above event. It also discusses current events, actions going forward, a summary of experience in the implementation of maintenance guidance provided in Tech Tip TT-VS-1247B and the amendment of Varian's service license, No. 45-30957-01.

1. Root cause

Varian Medical Systems, Inc. has concluded that the root cause for these events is that we did not properly evaluate the necessity to routinely clean specific components in the source wire path and include this action in the maintenance schedule.

Basis for root cause

In correspondence dated May 11, 2009, Varian provided the probable cause in accordance with 10 CFR 30.50 (c)(2)(i) as the jamming of the source wire in the VariSource unit is the accumulation of debris in the small bore of the wedge block above the V-drive.

During the past 6 months Varian has conducted extensive analyses of the materials and components involved in the jammed wire events. These are found in the submittals dated February 13, 2009 and May 11, 2009. There is no singular common element that ties the three events together. There may be a contributing probability from any of the following, but there is no evidence that any one is the root of the problem.

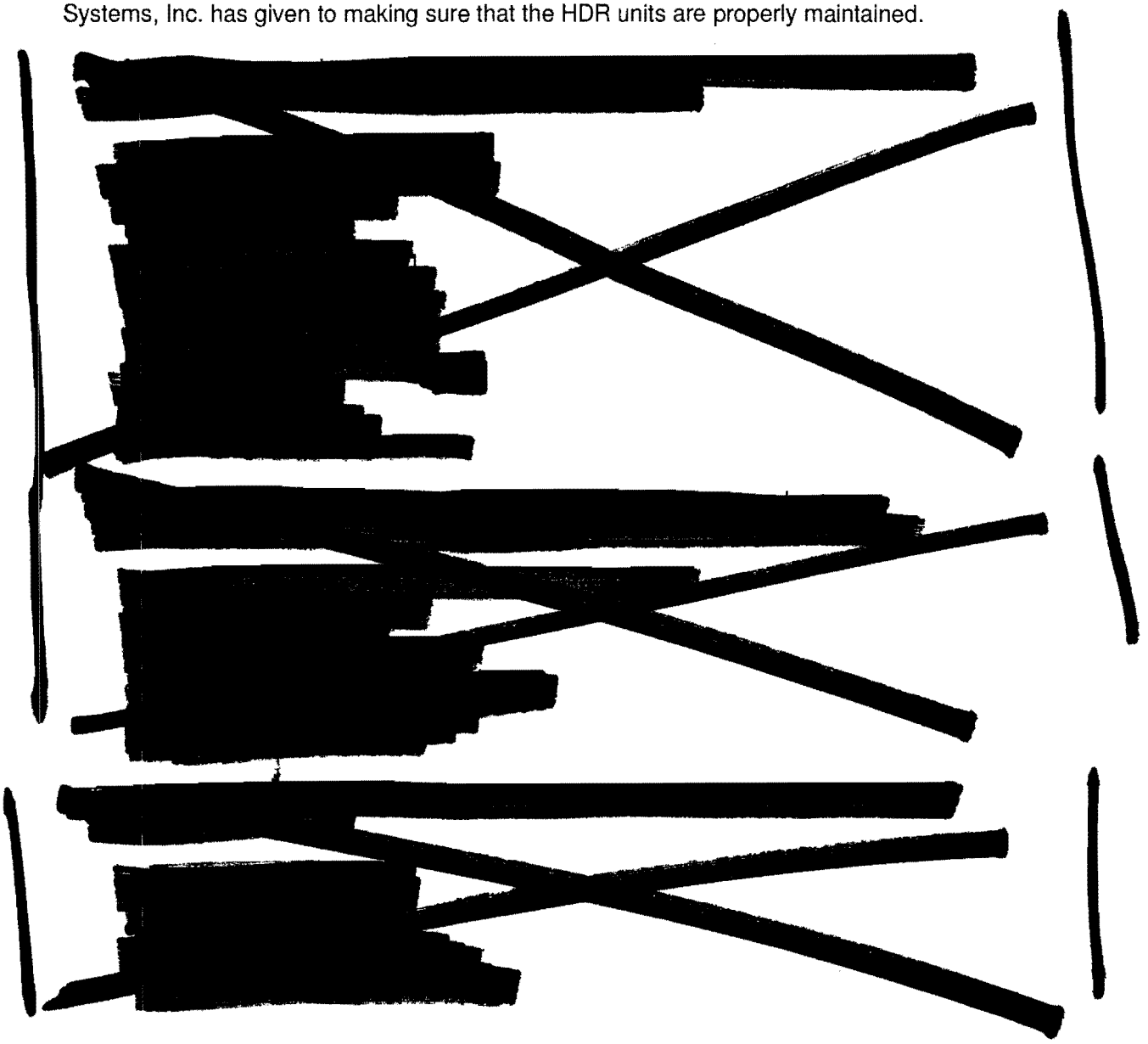
[redacted] wedge block lot that is installed in the units affected
d. Anodization process for the wedge block
e. Applicator selection and use by the hospital
f. Sterilization techniques used on applicators by the hospital
g. Other activities and actions at the hospital site that may contribute
h. Source wire manufacturing processes
i. Source wire handling
j. Use of thread locking compounds
k. Material incompatibility
l. Use of lubricants
m. Contamination during packaging or transportation
n. Relationship of error codes to HDR units that had jammed wires

The analysis of all data points to the need to include scheduled cleaning of specific components to mitigate the risk of a recurrence of this type of event.

Examples of current maintenance

There are many existing routine maintenance procedures that are conducted on varying schedules. The inclusion of additional maintenance activity as detailed in Tech Tip TT-

VS-1247B "Removing Dirt Build Up" addresses this important issue. Examples of current maintenance are given below and reflect the attention that Varian Medical Systems, Inc. has given to making sure that the HDR units are properly maintained.



2. Current conditions and actions going forward

Varian Medical Systems, Inc. notified the NRC as soon as we realized there was a problem. Our response to each event was immediate and radiation safety was the highest priority. Source wires were recovered with low radiation doses to all participants and similarly, the cumulative dose was low.

Importantly, no patients were involved in any of the events, and each site was back up and running in short order.

Customer Technical Bulletin CTB-VS-640A, "Potential for a source wire path constriction inside the VariSource HDR afterloader" was issued on February 3, 2009 and sent to all VariSource users. The CTB is included in the HDR unit documentation that all new customers receive.

Varian promptly developed and implemented Tech Tip TT-VS-1247B and it has been in use for 7 months at the 28 sites of interest, and has been expanded to include the entire installed base of VariSource units as preventive maintenance that is conducted every fourth source exchange. Note that source exchanges are typically performed every 13 weeks, though a very few sites have source exchanges every 17 weeks.

Each time the Tech Tip is executed at one of the 28 sites of interest, a spreadsheet report is completed that captures important information about what the service representative observed (discussed in Section 3 below). We are using this data in our continuing evaluation of these events to ensure the effectiveness of the Tech Tip. There has not been a recurrence and we believe the maintenance prescribed in the Tech Tip is appropriate.

The events have been thoroughly reviewed with all Field Service Representatives and they understand the importance and significance of the event. The most recent training was provided to all service representatives in May 2009.

Varian is continually developing new products and we confirm that the applicable Lessons Learned stated in the May 11, 2009 correspondence are of utmost importance in any new product line. These include:

a. Ensure that all bores and constrictions the source wire passes through are appropriately sized.

b. Evaluate areas where debris can collect and determine if the collection point is critical.

c. Ensure that the emergency retract handle can retract the source to the unit's tungsten shield in all reasonable scenarios.

d. Ensure that physical layout and access to important components is clear and unobstructed in keeping with ALARA.

e. Ensure that the scheduled maintenance addresses the need to clean debris that may collect in specific components.

Following the three events we conducted exhaustive analyses of components and materials that were used in the manufacture and ongoing use of the HDR unit including source wire manufacturing and consumables such as lubricants. We relied on in-house expertise as well as contracted outside engineering and analytical firms to provide expert independent analyses and opinions. Hospitals were also contacted by Technical Support to investigate everything from cleaning fluids that were used by janitorial services to applicator sterilization techniques looking for any contributing factor.

3. Summary of experience in applying the Tech Tip maintenance procedure

The maintenance prescribed in the Tech Tip is being applied at each source exchange at 28 sites of interest based on the cluster of the three events that had a jammed wire, and one event that may have been a pre-cursor event.

The data in the spreadsheet captures the following information:

a. Site name and unit serial number
b. Name of the service representative
c. The number of times a position verification test was run
d. Did the service representative notice unusual wire movement?
e. The number of active wire cycles since the last source exchange
f. Number of slippage errors (1A errors) in the past 3 months
g. The number and type of trouble and emergency service calls in the past 3 months
h. Difficulty of cleaning the wedge block bore
i. Amount of debris that has collected in the wedge block
j. Location of the most abundant amount of debris
k. Confirmation that the Tech Tip was properly executed
l. Comments on the condition of the old source wire
m. Comments on difficulty in loading the dummy wire
n. Statement of whether or not the customer has noticed any unusual wire movement

The information in the spreadsheet provides a good description of what is being seen in areas of the source wire pathway. The data indicates:

a. There have been no slippage errors at any of the sites
b. Only one trouble call occurred and that was not related to these events.
c. Active wire cycles range from a low of 55 to a high of 943 with no problems at any site
d. Debris tends to collect most at the home switch and V-drive funnel. Both locations are subject to cleaning in accordance with the Tech Tip.
e. All old source wires were visually normal after 3 months of use.
f. The customers did not notice any unusual source wire or dummy wire movements.

4. License amendment to include Tech Tip

At the request of the NRC, we are amending our license to include Tech Tip TT-VS-1247B. This is being sent to USNRC Region I under separate cover.