7.

ML091740334 VARIAN Medical Systems

30-Day Report for Event 44774 dated 2/13/2009

VARIAN
medical systems

BrachyTherapy
700 Harris Street
Suite 109
Charlottesville, VA 22903
USA
tel +1 434 977 8495
fax +1 434 244 7181
www.varian.com

February 13, 2009

Document Control Desk
US Nuclear Regulatory Commission
11555 Rockville Pike
Rockville MD 20852

Re: Contents of this mailing

This mailing contains the following documents.

1. 30-day report for Event 44774 – VariSource
2. 30-day report for Event 44790 - GammaMed
3. A proprietary filing providing additional information related to the above reports
4. Attachment VS 28 Sites
5. Attachment VS All Sites
6. Attachment Chron-1
7. Attachment Intertek-1
8. Attachment CTB-1
9. Attachment TT-1

Please contact me at 434.951.8675 or email to [redacted] as needed.

Very truly yours,

Richard G. Piccolo, CHP
Brachytherapy RSO

Copy: Regional Administrator
USNRC Region I
475 Allendale Road
King of Prussia, PA 19406

VARIAN
medical systems

BrachyTherapy
700 Harris Street
Suite 109
Charlottesville, VA 22903
USA
tel +1 434 977 8495
fax +1 434 244 7181
www.varian.com

February 12, 2009

Document Control Desk
US Nuclear Regulatory Commission
11555 Rockville Pike
Rockville MD 20852

Re: 30-day report – Written Notification for 10 CFR 30.50 and 10 CFR 21.21
Event 44774 – VariSource Event

Varian Medical Systems, Inc. is submitting this Written Notification in accordance with 10 CFR 30.50 and 10 CFR 21.21 addressing Event 44774. Facsimile notification was sent to the USNRC on January 14, 2009.

The contents of the document entitled "Proprietary filing" are company confidential and should not be released to the public without our written consent. It is being submitted to provide the NRC with additional information about the events, and actions that have been undertaken in the investigation and mitigation of them.

Please contact me at (434) 951-8675, or email [redacted]

Very truly yours,

Richard G. Piccolo

Richard G. Piccolo, CHP
Varian Brachytherapy RSO

Copy: Regional Administrator
USNRC Region I
475 Allendale Road
King of Prussia, PA 19406

Part 30 Filing

This report is filed in accordance with 10 CFR 30.50 (c)(2) addressing Event 44774 and uses the numbering system therein.

1. A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

Description of event

The Ir-192 source wire becomes jammed internally in the HDR unit and the source is left in an unshielded position outside of the HDR unit.

Three events occurred in December 2008 and each immediately followed a normally scheduled source exchange. They occurred when the Varian FSE (Facility Service Engineer) was conducting Positional Verification Testing that is a normal part of the source exchange. In each case the emergency handcrank was successfully used to return the source to the shielded position.

This type of event has never occurred before in the history of the VariSource HDR unit.

In each event Varian sent additional personnel to the site to assist the FSE in source recovery. All work was planned and conducted to ALARA principles. The detail of the source recovery at each site is considered company confidential and is being provided to the NRC under separate cover.

Probable cause

The probable cause of the event is the accumulation of debris in the bore of what is known as a wedge block. The debris compacted and then tightly bound the source wire preventing its proper retraction into the HDR tungsten safe.

Manufacturer and model numbers

The VariSource HDR Afterloader is manufactured by:

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

Model numbers of units involved – VariSource 200 (Southwest Regional and Stanford) and VariSource iX (Hershey)

2. The exact location of the event

a) Southwest Regional Cancer Center, 901 W 38th St, Austin TX

b) Hershey Medical Center, 500 University Drive, Hershey PA

c) Stanford University Medical Center, 820 Quarry Rd, Stanford, CA

3. The isotopes, quantities, and chemical and physical form of the licensed material involved

Isotope – Ir-192

Quantities – a) Southwest Regional Cancer Center - 9.2 Ci

b) Hershey Medical Center - 9.6 Ci

c) Stanford University Medical Center - 8.1 Ci

Chemical and physical form – sealed metallic source

4. Date and time of the event

a) Southwest Regional Cancer Center, December 2, 2008 – approximately 8:35 p.m. EST.

b) Hershey Medical Center – December 11, 2008 – approximately 12:30 p.m. EST.

c) Stanford University Medical Center – December 30, 2008, approximately 11:30 p.m. EST.

5. Corrective actions taken or planned and the results of any evaluations or assessments

As a preface to this discussion please note that the VariSource 200 series is no longer in production and serial number 462 is the last serial number of that model line. The new model VariSource iX began production with serial number 500.

The initial investigation focused on HDR units bound by serial numbers 435 through 462. The basis for this action is two-fold.

First – the serial numbers of HDR units that experienced the jammed wires are in a tight cluster – 435 (Stanford), 447 (Austin) and 448 (Hershey). Unit 445 (University of Nebraska) also experienced unusual source wire movement that we consider to be a precursor event.

Second – a lot of 39 wedge blocks has been identified that was used in the build of VariSource units in a run of serial numbers of 435 through

462. This series of serial numbers captures those units that experienced jammed wires and the precursor event.

The range of serial numbers was expanded by 5 on either end to provide a buffer and the list of sites of interest was amended to include serial numbers 430 through 505. (Again, note that the numerical range of serial numbers encompasses 75 units. However, in this range there are only 28 units in the United States. The remaining units are either located outside of the U.S., are serial numbers not issued or are in demonstration units that will not be used clinically.)

The list of 28 sites in the United States is considered company confidential and is being sent to the NRC under separate cover and entitled "List of affected sites in the United States."

The list of all VariSource sites in the United States is considered company confidential and is being sent to the NRC under separate cover and entitled "List of all VariSource sites in the United States."

Short term corrective action – Two short term corrective actions were initiated.

a) On December 23, 2008 a new maintenance instruction was issued to Field Service Engineering. The maintenance instruction was converted to a Tech Tip which is another method used to issue procedures. Tech Tip TT-VS-1247A was issued on January 7, 2009 and was re-issued as TT-VS-1247B on January 14, 2009.

The Tech Tip provides specific how-to direction for the removal of the debris in five locations where it is known to accumulate. A copy is attached as TT-1.

The implementation of the Tech Tip focused on the 28 sites in the U.S and as of February 12, 2009 the Tech Tip has been applied at 26 sites. It will be completed at all 28 sites by February 13, 2008.

b) Customer Technical Bulletin CTB-VS-640A, entitled "Potential for a source wire path constriction inside the VariSource HDR afterloader" was approved on February 5, 2009 and issued to all VariSource users in the United States and worldwide. The CTB addresses all VariSource models - ID, 200 and iX. A copy of the Customer Technical Bulletin is attached as CTB-1. The CTB will be tracked for receipt in the U.S.

The CTB will be part of the documentation provided to new VariSource customers.

Long term corrective action

The Tech Tip will be instituted as part of normal and routine maintenance at all VariSource sites in the U.S.

The 28 units in the serial number range of interest will have the Tech Tip implemented at every source exchange – typically every 13 weeks. The balance of the VariSource installed base will have the Tech Tip implemented every 4th source exchange. This is an average of once per year, though a few sites will have a 4th source exchange more frequently, and another subset may see the 4th exchange every 68 weeks since some sites have source exchanges every 17 weeks.

Alternate long term corrective action may be implemented depending on the outcome of Varian's ongoing investigation.

6. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

a) Southwest Regional Cancer Center, Austin TX – One Varian employee, 260 mrem whole body, 640 mrem extremity based on OSL dosimeter badge reading.

b) Hershey Medical Center, Hershey PA – Three Varian employees, 102 mrem whole body, 175 mrem extremity based on OSL dosimeter badge reading.

c) Stanford University Medical Center, Stanford, CA – Three Varian employees, approximate cumulative dose is 45 mrem whole body based on electronic dosimeter.

Part 21 Filing

Written notification in accordance with 10 CFR 21.21 (d)(3)(ii) and § 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 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 200 and Model 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 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.

Engineering evaluation has determined the following:

a. Compacted debris was found in source guide fixtures near the source drive. The source wire passes through a small bore in these fixtures

b. The debris is at least partly composed of materials that are used in source wire and applicator production as well as transfer guide tubes. Finding these materials showed that an unexpected contaminant was not present as far as we could determine. However, analyses are continuing to determine if any unexpected contaminants are present.

c. 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 compacted debris is responsible in jamming the wires and preventing them from retracting properly.

d. The source wires at the three sites were made from the inventory of stock 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.

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

f. The integrity of the source wire has not been compromised in any of these events. This has been determined through visual and mechanical inspection of affected wires.

g. 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:

- total collective dose equivalent from 3 events – 407 mrem
- 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 and the trend was identified after the third event which occurred on December 30, 2008.

Varian's RSO contacted the NRC on January 6, 2008 to discuss the events for clarification related to filing a report pursuant to 10 CFR 21.21. The NRC advised that a Part 21 filing would be appropriate and the initial notification was made by fax to the NRC Operations Center on January 14, 2009.

On January 15, 2009, Varian's RSO contacted another NRC staff member to discuss the applicability of reporting these events under §30.50(b)(2) and was advised that the citation did apply. Varian's RSO telephoned the NRC Operations soon thereafter and made a report pursuant to §30.50(b)(2).

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.

As a preface to this discussion please note that the VariSource 200 series is no longer in production and serial number 462 is the last serial number of that model line. The new model VariSource iX began production with serial number 500.

The initial investigation focused on HDR units bound by serial numbers 435 through 462. The basis for this action is two-fold.

First – the serial numbers of HDR units that experienced the jammed wires are in a tight cluster – 435 (Stanford), 447 (Austin) and 448 (Hershey). Unit 445 (University of Nebraska) also experienced unusual source wire movement that we consider to be a precursor event.

Second – a lot of 39 wedge blocks has been identified that was used in the build of VariSource units in a run of serial numbers of 435 through 462. This series of serial numbers captures those units that experienced jammed wires and the precursor event.

The range of serial numbers was expanded by 5 on either end to provide a buffer and the list of sites of interest was amended to include serial numbers 430 through 505. (Again, note that the numerical range of serial numbers encompasses 75 units. However, in this range there are only 28 units in the United States. The remaining units are either located outside of the U.S., are serial numbers not issued or are in demonstration units that will not be used clinically.)

The list of 28 sites in the United States is considered company confidential and is being sent to the NRC under separate cover and entitled "List of affected sites in the United States."

The list of all VariSource sites in the United States is considered company confidential and is being sent to the NRC under separate cover and entitled "List of all VariSource sites in the United States."

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 – Two short term corrective actions were initiated.

a) On December 23, 2008 a new maintenance instruction was issued to Field Service Engineering. The maintenance instruction was converted to Tech Tip which is another method used to issue procedures. Tech Tip TT-VS-1247A was issued on January 7, 2009 and was re-issued as TT-VS-1247B on January 14, 2009.

The Tech Tip provides specific how-to direction for the removal of the debris in five locations where it is known to accumulate. A copy is attached as TT-1.

The implementation of the Tech Tip focused on the 28 sites in the U.S and as of February 12, 2009 the Tech Tip has been applied at 26 sites. It will be completed at the 28 sites by February 13, 2008.

b) Customer Technical Bulletin CTB-VS-640A, entitled "Potential for a source wire path constriction inside the VariSource HDR afterloader" was approved on February 5, 2009 and issued to all VariSource users in the United States and worldwide. The CTB addresses all VariSource models - ID, 200 and iX. A copy of the Customer Technical Bulletin is attached as CTB-1. The CTB will be tracked for receipt in the U.S.

The CTB will be part of the documentation provided to new VariSource customers.

Long term corrective action

The Tech Tip will be instituted as part of normal and routine maintenance at all VariSource sites in the U.S.

The 28 units in the serial number range of interest will have the Tech Tip implemented at every source exchange – typically every 13 weeks. The balance of the VariSource installed base will have the Tech Tip implemented every 4th source exchange. This is an average of once per year, though a few sites will have a 4th source exchange more frequently, and another subset may see the 4th exchange every 68 weeks since some sites have source exchanges every 17 weeks.

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. Alternate long term corrective action may be implemented depending on the outcome of Varian's ongoing investigation.

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.

Customer Technical Bulletin was approved and issued on February 5, 2009. A copy is attached as CTB-1.

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

Not applicable