



**Brachy Therapy**  
700 harris Street, Suite 109  
Charlottesville, VA 22903  
USA  
tel +1 434 977 8495  
fax +1 434 244 7181  
www.varian.com

October 19, 2009

3036666

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

Re: Affidavit submitted IAW 10 CFR 2.390  
Varian Medical Systems, Inc.  
Event 44774

The following documents have been submitted to provide information related to two events involving High Dose Rate Afterloaders manufactured by Varian Medical Systems, Inc. Event 44774 is related to the VariSource HDR unit. Event 44790 is related to the GammaMed HDR unit.

Varian Medical Systems, Inc. (hereinafter Varian) requests that the following list of documents be withheld from public disclosure under 10 CFR 2.390. In accordance with 10 CFR 2.390 (b)(1)(ii) the following is provided in support of this request.

**A) Documents to be withheld – Please withhold the following documents in their entirety.**

1. ADAMS Accession No. ML091730597 VMS Tech-Tip: Removing Dirt Build Up; updated 1/8/2009
2. ML091740321 Facsimile Notification dated 1/14/2009 titled Initial Notification for 10 CFR 21 Report Filing
3. ML090230580 List of Sites in US; excel spreadsheet attached to email dated 1/22/2009
4. ML090260100 email dated 1/22/2009; VariSource Maintenance Schedule (contains Tech-Tip)
5. ML091730482 email dated 2/2/2009; titled: Monday update; contains pictures of analysis
6. ML091740324 VariSource Customer List (28 Suspect Sites)
7. ML091740334 VARIAN Medical Systems 30-Day Report for Event 44774 dated 2/13/2009

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8. ML09174044 Letter dated 5/11/2009 titled: Results of Ongoing Investigations Related to the VariSource and GammaMed Events
9. ML091740484 LER 09-009-00 Letter dated 5/11/2009 titled: Results of Ongoing Investigations Related to the VariSource and GammaMed Events (same as above but with NRC forms attached to the front)
10. ML092080150 Letter dated 7/23/2009 Varian Medical Systems, Inc., Event 44774
11. ML092580179 Letter dated 8/26/2009 Varian Medical Systems, Inc. Event 44774 with enclosures
12. Three documents that are attached and being resubmitted to the NRC. Each is identified as "Confidential". This information was originally contained in the February 13, 2009 submittal as:
- a. ATTACHMENT – VS ALL SITES
  - b. ATTACHMENT – Chron – 1
  - c. ATTACHMENT INTERTEK 1

**B) Official position of the person making the affidavit**

Richard G. Piccolo, Radiation Safety Officer

**C) The basis for proposing the information to be withheld**

The documents identified contain trade secrets and other information that is important to Varian's business.

Customer lists – several documents contain partial or complete lists, or otherwise identify Varian HDR customer sites. This information would be valuable to our competitors.

Maintenance procedures – these procedures identify components in our equipment that are critical to the operation and use of the HDR unit. Some are patented and some are secret. If these procedures were made public our competition would know both the engineering and designs that provide us with competitive advantages.

Photographs of components – release of this information would provide our competitors with specific visual information about how components are juxtaposed and designed.

Specifically, the documents contain:

1. *ADAMS Accession No. ML091730597 VMS Tech-Tip: Removing Dirt Build Up; updated 1/8/2009*

Contains photographs of proprietary components

*2. ML091740321 Facsimile Notification dated 1/14/2009 titled Initial Notification for 10 CFR 21 Report Filing*

Identifies specific customer sites that our competitors could exploit or target for business.

*3. ML090230580 List of Sites in US; excel spreadsheet attached to email dated 1/22/2009*

Identifies customer sites in the United States and the names of Varian Field Service Representatives.

*4. ML090260100 email dated 1/22/2009; VariSource Maintenance Schedule (contains Tech-Tip)*

This document identifies components and maintenance schedules that are proprietary and secret.

*5. ML091730482 email dated 2/2/2009; titled: Monday update; contains pictures of analysis*

This document contains pictures and cutaways of secret or otherwise confidential HDR unit components.

*6. ML091740324 VariSource Customer List (28 Suspect Sites)*

Identifies customer sites that our competitors could exploit or target for business

*7. ML091740334 VARIAN Medical Systems 30-Day Report for Event 44774 dated 2/13/2009*

Provides specific customer information, lists of serial numbers of units affected and under investigation, provides secret or otherwise confidential information related to source wire manufacturing, includes photographs of components that are secret or otherwise confidential.

*8. ML09174044 Letter dated 5/11/2009 titled: Results of Ongoing Investigations Related to the VariSource and GammaMed Events*

Identifies components in the HDR unit that are secret or otherwise confidential, identifies maintenance techniques that are unique to our equipment, identifies customer names as well as the HDR applicators that they use, provides specifics about the differences between Varian's HDR units and in doing so highlights specifics about the way the units are designed, how the sources are constructed including specifics on geometry and materials as well as lessons learned and how they will be analyzed in future Varian products.

9. ML091740484 LER 09-009-00 Letter dated 5/11/2009 titled: Results of Ongoing Investigations Related to the VariSource and GammaMed Events (same as above but with NRC forms attached to the front)

See #8 above.

10. ML092080150 Letter dated 7/23/2009 Varian Medical Systems, Inc., Event 44774

Identifies specifics about source wire construction, provides specifics about maintenance and identifies components that are secret or otherwise confidential, provides summary information related to customer use of the afterloader at 28 sites of interest.

11. ML092580179 Letter dated 8/26/2009 Varian Medical Systems, Inc. Event 44774 with enclosures

Largely expands the information in #10 above. Includes specific site names as well as the names of our Field Service Engineers, provides a maintenance checklist that identifies components and their maintenance frequency, provides portions of the VariSource Service Manual which includes a Table of Contents, the Service Schedule is included as well as photographs of components.

12. The following three documents are being resubmitted to the NRC. Each is identified as "Confidential". This information was originally contained in the February 13, 2009 submittal as:

- a. ATTACHMENT – VS ALL SITES
- b. ATTACHMENT – Chron – 1
- c. ATTACHMENT INTERTEK 1

Please include these additional documents in the scope of this withholding request. The basis for each is as follows:

- a. VS ALL SITES contains the complete customer list for all VariSource customers in the United States
- b. Chron-1 contains customer information (how many source wire extensions they had in several 3-month periods) as well as information related to source exchange frequency and error codes they encountered.
- c. INTERTEK 1 contains specific information about components and processes used in their manufacture and maintenance that are company secrets or otherwise protected.

**D) Statement of the harm that would result if the information is disclosed**

These documents contain customer lists, trade secrets and information on the engineering and design of the HDR unit, the sources that are used, maintenance frequency, identification of critical components, source construction and other secrets related to same. Release of this information would provide our competitors with

information that could be used to target our customers or to deconstruct the engineering that went into our devices and reduce competitive advantages.

**E) Location of information in the documents.**

This information is contained throughout the documents in their entirety.

Very truly yours,

A handwritten signature in black ink that reads "Richard G. Piccolo". The signature is written in a cursive style with a large, prominent initial "R".

Richard G. Piccolo, CHP  
Varian Brachytherapy RSO

**Enclosures:**

- a. ATTACHMENT – VS ALL SITES
- b. ATTACHMENT – Chron – 1
- c. ATTACHMENT INTERTEK 1

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