



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Flanigan Square, 547 River Street, Troy, New York 12180-2216

Antonia C. Novello, M.D., M.P.H., Dr.P.H.  
*Commissioner*

Dennis P. Whalen  
*Executive Deputy Commissioner*

April 6, 2005

**RE: LINAC/IMRT Significant Misadministration – Software Error Suspected  
(Notice No. BERP 2005-1)**

Dear Linear Accelerator Registrant:

The New York City Department of Health and Mental Hygiene, Office of Radiological Health issued a notice to its registrants in regard to a significant misadministration which occurred in its jurisdiction. A copy of that notice is attached.

Preliminary information indicates that an error with the Varian VARIS software may have resulted in corruption of the multi-leaf collimator data used for the patient's treatment. Each facility should also review the procedures that are utilized for verification that the radiation field is of the appropriate size and shape during the delivery of each IMRT fraction.

Please review the notice and implement any actions that may be prudent. This notice is being sent to you for informational purposes, therefore, a response is not required. However, if you have experienced a similar software problem, regardless if it involved a patient, please contact this office.

If you have any questions or comments, please call John O'Connell, Janaki Krishnamoorthy, Ph.D., or me at (518) 402-7590, e-mail us at [berp@health.state.ny.us](mailto:berp@health.state.ny.us) or write to:

New York State Department of Health  
Bureau of Environmental Radiation Protection  
Radioactive Materials Section  
547 River Street, Flanigan Square – Room 530  
Troy, New York 12180-2216

Sincerely,

Robert E. Dansereau, Chief  
Radioactive Materials Section  
Bureau of Environmental Radiation Protection

RD/JO:ks

Attachment

**NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
OFFICE OF RADIOLOGICAL HEALTH  
2 LAFAYETTE ST, 11<sup>TH</sup> FLOOR**

**NEW YORK, NY 10007**

**March 25, 2005**

ORH INFORMATION NOTICE 2005-01

**Addressees**

All Holders of Therapeutic Radiation LINAC Unit Certified Registrations

**Purpose**

We are issuing this Information Notice to inform certified registrants operating therapeutic radiation LINAC units of a significant misadministration which occurred during treatment utilizing the Varian VARIS oncology information system. The exact cause of the occurrence is still under investigation by Varian, but the circumstances of the event are serious enough to warrant early notification. All Users of Varian treatment systems must be alert to the existence of a system flaw with the potential of leading to a very high overdose.

**Description of Circumstances**

On March 14, 15 and 16, 2005, a patient received fractionated treatments for base of the tongue cancer. Normal review protocols were followed. The Prescribed dose per fraction was 2 Gray, using a 5-field IMRT technique. A revised treatment plan was developed by a physicist and approved by a physician to reduce dose to the teeth. Analysis revealed that the dynamic multileaf collimators were wrongly in the open position during the three treatments. A dose calculation revealed that the patient received three fractionated treatments in the range of 13-14 Gy per treatment to a volume between the base of the skull and the larynx. Total dose received was approximately 39-42 Gy.

Preliminary information indicates that a software error resulted in corruption of the MLC data used for this patient's treatment. Although the dynamic MLC files were missing at the time of treatment, they are shown connected to the treatment fields in the Varian VARIS patient management software. Also, the Treatment Field Setup Report showed that the MLC was present in the treatment fields when in fact it was not. When the User tried to access the MLC file the Varian software crashed each time.

Varian notified the FDA on March 22, 2005. It is understood that Varian will submit a Medical Device Report to FDA when they have completed their investigation.

**March 25, 2005**

ORH INFORMATION NOTICE 2005-01 (cont'd)

**Effects of Misadministration**

The report of misadministration lists possible sequelae in 2 phases. These include a number of serious effects, although the report does not predict the likelihood or severity of each of the possible problems.

**Action**

Although treatment plans are entered which should cause multileaf collimators to be in place, the VARIS system may not properly actuate collimators. This has resulted in a serious radiation overexposure. All Users of Varian treatment systems utilizing the multifield IMRT technique must be aware of this defect with the multileaf collimators, and must be certain that their systems are not affected by this problem before scheduling further treatments.

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