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 19, 2005

RE: UPDATE: LINAC/IMRT Significant Misadministration – Software Error Suspected (Notice No. BERP 2005-2)

Dear Linear Accelerator Registrant:

On April 6, 2005, a Notice (BERP 2005-1) was sent to you with regard to a significant misadministration that occurred during the delivery of an IMRT treatment. The Notice indicated that an error might have occurred in the Varian VARIS software which resulted in corruption of the data used to control a multi-leaf collimator. The purpose of this notice is to provide updated information.

Varian Medical Systems representatives, including engineering, service, applications, education and quality personnel, conducted an investigation. Varian concluded that the Varian software performed as expected and was not the cause of this misadministration. Copies of Varian's summary analysis and open letter dated April 4, 2005 are enclosed. A complete analysis is available from Varian Medical Systems and can be obtained by contacting Kolleen T. Kennedy, Vice President, Oncology Division at (650) 424-6235 or e-mail at *kolleen.kennedy@us.varian.com*.

This event, along with others that have occurred, mandates that we remind facilities of the absolute necessity to verify that the radiation field is of the appropriate size and shape prior to the patient's first treatment. Facilities are also reminded of the need to perform a second check of the treatment plan, calculations, and/or data input into a Record and Verify System before treatment begins, and therapists must closely monitor the console/ visual indicators during treatments.

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.

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* 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

Attachments