

April 24, 2000

**PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE** PNO-I-00-010

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by Region I staff in King of Prussia, Pennsylvania on this date.

**Facility**

University Of Maryland Medical Systems  
Univ Of Maryland Medical Systems  
Baltimore, Maryland  
License No: MD-07-014-05

**Licensee Emergency Classification**

Notification of Unusual Event  
Alert  
Site Area Emergency  
General Emergency  
X Not Applicable

Subject: GAMMA KNIFE MISADMINISTRATION

At approximately 3:00 p.m. on April 21, 2000, the Maryland Department of the Environment's Radiological Health Program (MDE-RHP) notified the NRC Operations Center that on April 20, 2000, a 52-year-old female patient received a medical misadministration during a gamma knife procedure for treatment of a brain tumor at the University of Maryland Medical Systems (UMMS) in Baltimore. The patient received a dose of 12.6 grays (1260 rads) to an unintended site of approximately 0.18 cubic centimeters. The unintended site was approximately 4.2 centimeters from the intended site.

The medical directive for this treatment was defined as approximately 18 grays administered over six treatment fractions. The misadministration occurred during the first treatment fraction. Based on preliminary information, it appears that the Y and Z coordinates were reversed during the manual adjustment of the coordinates on the device's stereo tactic frame. This frame adjustment is accomplished by loosening the frame via the use of allen screws and manually adjusting it. One person calls out the coordinate and the other conducts the adjustment. When the licensee started to set up for the second fraction, the error was noted. The treatment plan was reevaluated to include some partial dose to the tumor from the first fraction and the treatment was completed in seven fractions instead of six. The patient and her referring physician have been notified of this misadministration.

The gamma knife is not scheduled to be used again until April 25. A hospital management meeting is scheduled today with personnel from the Hospital Administration, Oncology, Neurosurgery and the Radiation Safety Office to discuss this incident. MDE-RHP requested that the licensee review previous medical files to assure that the reversal of coordinates has not happened before without a misadministration being identified. MDE plans to continue its investigation of this incident.

UMMS holds a specific license for the use of a gamma knife (Model 23016 Leskell Gamma System) for the radiation treatment of human patients from MDE-RHP. The State of Maryland is an Agreement State and has

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jurisdiction over the use of byproduct material within its borders.

MDE concurs with the technical content of this PN. This information is current as of 10:00 a.m., April 24, 2000. The Region I Office of Public Affairs is prepared to respond to media inquiries.

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