

February 15, 2000

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-II-00-007

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 II staff (Atlanta, Georgia) on this date.

Facility	Licensee Emergency Classification
Healthsouth Doctor's Hospital, Inc.	Notification of Unusual Event
(An Agreement State Licensee)	Alert
Coral Gables, Florida	Site Area Emergency
License No: 2301-2	General Emergency
	X Not Applicable

Subject: MEDICAL MISADMINISTRATION

The Florida Bureau of Radiation Control (BRH) reported to the Headquarters Operations Center on February 14, 2000, that a medical misadministration had occurred at the licensee's facility on January 25, 2000. An adult patient diagnosed with metastatic lung disease and up to 80 brain lesions was being treated with a stereotactic radiosurgery procedure using the Leksell Gamma System, Model 23016 gamma knife and was undergoing the fourth of five planned treatments when the event occurred. The event resulted in one treatment site (lesion site 16) receiving a second unintended treatment of 12 gray for a total dose of 24 gray.

The error was discovered by the licensee on January 28, 2000, during the licensee's routine quality assurance review of the treatment, and reported to the BRH on January 28, 2000. The BRH conducted an on-site investigation on February 2, 2000, which included a review of the treatment plans, the written directive, physician approval procedures and a reenactment of a treatment plan for the remaining untreated sites. The event was determined to be caused by human error when the wrong site was selected in the computer. There was no malfunction of the gamma knife or computer equipment. The licensee has reported to the BRH that the additional dose has not caused any harmful effects in the patient.

An abnormal occurrence report has been prepared by the BRH and provided electronically to the Office of State Programs.

This information is current as of 11:30 a.m., Tuesday, February 15, 2000.

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