August 7, 2003

This event is not available for public disclosure per Agreement State request until 08/11/03

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-II-03-013

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**
Medical University of South Carolina	Notification of Unusual Event
(An Agreement State Licensee)	Alert
Charleston, SC	Site Area Emergency
License: 081	General Emergency
	X Not Applicable

Subject: BRACHYTHERAPY PROCEDURE EVENT

The South Carolina Bureau of Radiological Health (the Bureau) notified the NRC Operations Center that the licensee had reported an event involving a Low Dose-Rate Brachytherapy procedure. The procedure involves the administration of iodine-125 liquid into a balloon that has been surgically inserted into a patient's skull, and the iodine-125 liquid is removed after a designated period of time.

The patient was administered 325 millicuries of liquid iodine-125 on July 31, 2003, and the liquid was to be removed on August 5, 2003. At the termination of the procedure on August 5, 2003, only 31.5 millicuries could be removed. The licensee and the manufacturer's representative conducted an investigation and determined that the balloon had not ruptured, and was not leaking. The balloon device is being returned to the manufacturer for further evaluation. The licensee reported that radiation surveys around the patient were normal at the beginning of the procedure; however, a survey of the patient's bladder was higher than normal on the last day of the procedure, and that some contamination was noted on the patient's pillow. The licensee has been unable to account for the loss of material, and believes that there was a slow leak of liquid from the injection site on the patient's skull. The licensee and the manufacturer are continuing their evaluation and a report on the incident will be prepared by the licensee.

The Bureau is continuing their evaluation of the event.

Region II received initial notification of this occurrence from the NRC Operations Center. This information has been discussed with the Bureau and is current as of 4:00 p.m., Thursday, August 7, 2003.

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