

April 3, 2006

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-06-008

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 the Region III staff on this date.

Facility

Indiana University Medical Center
Indianapolis, Indiana
License: 13-02752-03

Licensee Emergency Classification

Notification of Unusual Event

Alert

Site Area Emergency

General Emergency

Not Applicable

SUBJECT: MEDICAL EVENT INVOLVING INCORRECT BRACHYTHERAPY SOURCE POSITIONING

DESCRIPTION:

On March 30, 2006, the licensee's Radiation Safety Officer notified the NRC Operations Center of a brachytherapy medical event that occurred on March 29, 2006.

The medical event involved the use of a manual, low-dose-rate brachytherapy device. The device utilizes hinged hardware (bucket) that allows proper positioning of cesium-137 sources (sources) within the brachytherapy device for gynecological treatments. After removal of the sources from the patient, licensee staff noted that the bucket that was used for the treatment was too short for the brachytherapy device. Licensee staff subsequently determined that, since the bucket was too short, it did not position the sources correctly in the patient. The licensee determined that the incorrect positioning of the sources caused the dose delivered to the treatment site to differ from the prescribed dose by more than 20 percent, constituting a medical event. The licensee does not believe that the medical event will have any adverse effect to the patient.

In response to the medical event, the licensee reviewed all of the brachytherapy treatments that were conducted with the brachytherapy device. The licensee identified six additional treatments that involved similar, incorrect source positioning due to the use of buckets that were too short for the brachytherapy device. The licensee continues to conduct dose evaluations. Based on the licensee's preliminary dose evaluations, none of the additional six treatments resulted in a medical event because the doses delivered to the treatment sites did not differ from the prescribed doses by more than 20 percent.

NRC Region III inspectors will be at the licensee's facility in Indianapolis, Indiana, on April 3, 2006, to review the circumstances surrounding this medical event and the six other cases involving incorrect positioning of the sources.

The Office of Nuclear Materials Safety and Safeguards and the State of Indiana have been notified. The information in this preliminary notification has been reviewed with licensee management.

The licensee reported this event to the NRC Operations Center at 11:41 a.m. (ET) on March 30, 2006. This information is current as of 1:00 p.m. (ET) on April 3, 2006.

CONTACTS:

Darrel Wiedeman
(630) 829-9808

Robert Gattone
(630) 829-9823