March 29, 2002

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-IV-02-014A

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 IV staff on this date.

Facility
St. Bernard's Regional Medical Center
225 East Jackson Ave.
Jonesboro, AR 72401
License No.: ARK-365-BP-07-97
State of Arkansas Licensee

Licensee Emergency Classification
___ Notification of Unusual Event
___ Alert
___ Site Area Emergency
___ General Emergency
_X_ Not Applicable

SUBJECT: MEDICAL MISADMINISTRATION - UPDATE

DESCRIPTION: On March 7, 2002, the NRC was notified by the Arkansas Department of Health (ADH) of a therapeutic medical misadministration involving a the Novoste Beta-Cath System, a catheter-based brachytherapy system. The event occurred at St. Bernard's Regional Medical Center in Jonesboro, Arkansas.

On February 26, 2002, the licensee attempted to perform a vascular brachytherapy procedure involving a beta radiation source train containing a nominal activity of 2.22 gigabequerel (60 millicurie) of strontium-90. The radiation source train was contained in an enclosed catheter with a gold marker at each end of the source train. These markers are used for precise positioning of the source train. Following the initial attempt to administer the treatment to the intended site, the licensee discovered that one of the markers could not be seen under flouroscopy due to interference from a wire suture in the patient's sternum. Twenty-four seconds elapsed between the initial attempt and the return of the radiation source train to the delivery device. The licensee made two additional attempts to complete the treatment, but was unable to see both the markers, and returned the source train to the delivery system immediately. Because both markers could not be seen, the licensee could not establish the positioning of the sources at the treatment site; therefore, the licensee could not verify that an unintended area had not been treated with the sources.

On March 25, 2002, the ADH notified NRC that they had received the licensee's written report of the event. The licensee estimated a dose of 2.4 gray (240 rads) was delivered at a distance of 2 millimeters from the centerline of the source train and maintained that although one marker could not be seen they believed that the entire source train was delivered to the intended treatment site. The licensee concluded that the cause of the device failure was due to an inadequate connection of the treatment catheter or the fluid management system. The licensee developed corrective actions to prevent reoccurrence of a similar failure.

The ADH arranged for two qualified medical experts to review cine film images of the procedure. The ADH concluded that the event was a misadministration because the licensee could not confirm that the dose was delivered to the intended location. The patient and the referring physician were notified of the misadministration by the licensee. The ADH considers this event closed.

Region IV received notification of this occurrence from NRC's Operations Center on March 26, 2002.

Region IV has informed NMSS, STP, OEDO and Region IV's OPA and SLO.

This information has been discussed with the State and is current as of 3:15 p.m. (CST) on March 29, 2002.

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