DCS No.: 99999999030522
Date: June 20, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-I-03-017A

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 I staff on this date.

Facility
Union Memorial Hospital
Baltimore, Maryland

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

Docket No.: NA
License No.: Agreement State Licensee
Event Number: 39883

SUBJECT: UPDATE ON DRIVE MECHANISM MALFUNCTION OF AN INTRAVASCULAR BRACHYTHERAPHY DEVICE DURING PATIENT TREATMENT

During a cardiac brachytherapy procedure conducted at Union Memorial Hospital on the afternoon of May 22, 2003, there was a malfunction of the drive mechanism with a Guidant Galileo III intravascular brachytherapy (IVB) device containing approximately 95 millicuries of Phosphorus 32 (P-32). The console touch screen used to control the treatment froze and did not display the touch screen interrupt button. The licensee was unable to retract the source to its shielded position using the system stop button or the manual hand-wheel. After the attending physician removed the catheter and source from the patient, the power cord was removed from the wall receptacle and the source was retracted back to its shielded position. The licensee indicated that the source was in the patient for approximately 45 to 60 seconds. The manufacturer representative present during the treatment indicated that this period was 60 to 90 seconds.

The device was returned to the manufacturer for evaluation. Once returned to their Texas facility, the manufacturer was able to simulate a similar type of failure on two occasions and is focusing on a timer chip as the possible cause of the malfunction. The manufacturer indicated that this is the first failure of this type for this device and not a generic problem. At this point in their investigation, the manufacturer feels that the failure was caused by a hardware problem and not the device's software. The manufacturer is required to submit 30 day reports to the Texas Department of Health (TDH) and the Food and Drug Administration (FDA) the week of June 23.

The State of Maryland sent an inspector to the hospital on May 28 to conduct an investigation. Based on the preliminary results of their investigation, Maryland has ruled out human error as the cause of the drive mechanism malfunction. The licensee estimated a worst case dose to the wall of the patient's artery as approximately 1038 rads based on a 60 second exposure time. As a result of this incident, Maryland is considering implementing a requirement for all of their licensees with IVB devices to conduct annual emergency exercises.

On June 4, representatives from TDH and an FDA inspector conducted an on-site investigation at the manufacturer's facility. During the on-site investigation, TDH identified some potential hardware design changes to the device. The licensee will be submitting this change as an amendment to the unit's sealed source and device registration sheet. TDH and FDA asked the manufacturer if they planned to issue a notice alerting their customers to this type of malfunction. The manufacturer wanted to complete testing and evaluation prior to considering issuing such a notice. TDH is continuing its investigation.

On June 18, representatives from Region I, Region IV, the Office of Nuclear Materials Safety and Safeguards (NMSS), and the Office of State and Tribal Programs were briefed by the States of Maryland and Texas regarding the status of their investigations.

In response to this and several recent events, Region I has prepared an Information Notice (IN) on source positioning errors and system malfunctions during administration of intravascular brachytherapy treatments. The IN is currently under review by NMSS.

The States of Maryland and Texas concur with the contents of this notification. Region IV has been notified. Region I is prepared to respond to media inquiries.

This information in this notification is current as of 11:00 a.m. on June 20, 2003.

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