DCS No.: 99999999030522
Date: May 29, 2003

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

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: 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 malfunction occurred during the treatment of the third of three patients. The first two treatments were completed without any problems. The treatment of the third patient was initiated with the dummy source successfully reaching the proper dwell position (confirmed visually via the fluoroscopy screen) and returning to the cartridge. The active source was then advanced into the catheter, but when the licensee determined that the source movement light continued to blink well after the anticipated transit time, the licensee initiated a fluoroscopic view of the treatment site, and with no source in the field of view, the licensee assumed a machine malfunction had occurred and initiated emergency procedures. The licensee performed surveys which confirmed that the source stopped inside the patient. The indicator light on the console continued to indicate the source was in transit even after the licensee confirmed the source was in the patient and not at the treatment site. The licensee was unable to retract the source to its shielded position using the machine interrupt, the system stop button or the manual hand-wheel. At this point, the attending physician removed the catheter and source from the patient and dropped them on the operating floor. After the power cord was removed from the wall receptacle, the source was retracted back to its shielded position. The licensee indicated it took approximately 45 to 60 seconds to remove the source from the patient.

The source delivery unit was taken to the licensee's hot lab after the event and the daily quality assurance (QA) checks were performed in the physics and clinical modes. The unit passed both QA checks. The manufacturer representative present during the procedure immediately notified the manufacturer's technical center. The manufacturer is licensed and the device is registered by the Texas Department of Health (TDH), an Agreement State. The manufacturer notified TDH the afternoon of May 23, 2003. TDH contacted the NRC Operations Center the morning of May 27. Region I contacted the State of Maryland later the same day regarding this event. State of Maryland was unaware of this event since the licensee failed to notify them.

The device is in the process of being returned to the manufacturer for evaluation. A new device has been provided to the licensee. The manufacturer is required to submit a written report to TDH within 30 days. TDH continues to follow this event closely and will evaluate the manufacturer's report.

The State of Maryland sent an inspector to the licensee's facility on May 28 to conduct an investigation. The State's investigation is ongoing, but preliminary indications are that the staff in the operating room did not receive any significant dose from this event. The dose to the patient is still being evaluated by the licensee.

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.

The information in this notification is current as of 11:00 am on May 29, 2003.

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Region I Form 83
(Rev. April 2, 2003)