



"Larry Donovan"  
<LXD@nrc.gov>  
09/20/2006 07:24 AM

To <NMED@inel.gov>  
cc <dante.huntsman@inl.gov>, "Christi Maier"  
<MCM1@nrc.gov>, "Vivian Campbell" <VHC@nrc.gov>  
bcc

Subject Re: Information request for NMED item 060319

To answer your questions:

This medical event was caused by human error as the license did not verify that the sources were positioned in the proper location in the prostate. The urologist misidentified the anatomy visualized under the ultrasound guidance procedure and mistook the penile bulb and base of the penis to be the prostate. The inexperience of the urologist (this was the 6th case performed since the licensee received authorization to perform this procedure in December 2005) was a contributing factor.

#### Actions taken to Prevent Recurrence

Licensee -Based on the cause and contributing factors of the medical event, the licensee changed their procedures to include procedural modifications to include performing a fluoroscopic examination early in the procedure to ensure that the seeds are placed in the prostate; any question concerning differences in appearance of the ultrasound images obtained in the operating room and images obtained during a prior volume study will be resolved prior to commencing with the implant; and additional training, include proctoring on site, will be obtained before performing another implant. the licensee has suspended all implants of this nature indefinitely

>>> NMED@inel.gov 08/11/2006 9:14 AM >>>

We need additional information to complete the NMED record identified below. To promptly complete the NMED record, we request a reply at your earliest convenience, but no later than 60 days from the date of this request.

NMED Item No.: 060319  
Licensee/Reporting Party: BOZEMAN DEACONESS FOUNDATION  
License Number: 25-10994-04  
Event Date: 5/9/2006

#### ADDITIONAL INFORMATION REQUESTED

What was the cause of the event?

What corrective action(s) were taken by the licensee to prevent a recurrence?

Thank you for your help,

Dante Huntsman  
NMED Project  
Dante.Huntsman@inl.gov