"Wiedeman, Darrel"
<Darrel.Wiedeman@nrc.gov>

07/08/2010 08:21 AM

To "NMED@inel.gov" <NMED@inel.gov>

cc "Pelke, Patricia" <Patricia.Pelke@nrc.gov>, "Frazier, Cassandra" <Cassandra.Frazier@nrc.gov>, "Huston, Thomas E." <Thomas.Huston2@va.gov>, "Bloomer,

bcc

Subject FW: Information for Durham RE: NMED Item No. 090079

Dante: you requested additional information regarding the reported medical event at the VA Durham, North Carolina facility (NMED No. 090079). Attached is the information you requested to complete the NMED records. We now consider this issue closed, please close out NMED No. 090079

Darrel Wiedeman

From: Huston, Thomas E. [mailto:Thomas.Huston2@va.gov]
Sent: Thursday, July 08, 2010 9:14 AM
To: Wiedeman, Darrel
Cc: Frazier, Cassandra; Williams, Gary E; Offutt, Lisa M
Subject: Information for Durham RE: NMED Item No. 090079

Darrel,
Below are answers to NMED questions you forwarded to me on June 28, 2010, for VA Medical Center, Durham, North Carolina.

What was the model number of the seeds?
Seed model number is IAI-125A.

Who was the manufacturer of the seeds?
Seeds were manufactured by IsoAid, LLC.

Is the cause still unknown and still no corrective actions planned?
The medical event was reported because a D90 less than 80% of the prescribed dose was determined due to seed migration into peri-prostatic tissues. The cause of seed migration was not able to be determined. In this case, no corrective actions were taken or planned related to the implant process because seed migration, after documented initial correct seed placement, is beyond the control of the authorized user physician. As corrective actions related to medical event follow-up, the prostate dose was boosted with a make-up seed implant to provide good coverage. The composite post-op dosimetry has been documented and final dosimetric parameters were acceptable. Doses to the bladder wall, rectum, and peri-prostatic tissues were evaluated for the seeds that migrated out of the target volume. These doses were provided to NRC by NHPP in an e-mail dated March 23, 2010, and again by e-mail on April 6, 2010, and were all below levels of concern (i.e., less than 150% of expected dose).

Thomas E. Huston, Ph.D.
VHA National Health Physics Program
501-257-1578