"Courtemanche, Steven" <Steven.Courtemanche@nrc.gov>
08/12/2010 07:58 AM

To Dante C Huntsman <Dante.Huntsman@inl.gov>
cc "White, Duane" <Duane.White@nrc.gov>
bcc
Subject Additional Information for NMED Item No. 100290

History: This message has been replied to.

On August 5, 2010, you requested additional information on the above NMED Item Number.

(1) What was the cause of the event (human error?)? Human error caused the event as the surgeon incorrectly identified the location in the prostate to begin the implantation procedure.
(2) What corrective action(s) were taken to prevent a recurrence? This is still being evaluated.
(3) Who was the manufacturer of the I-125 seeds? The manufacturer of the Iodine-125 seeds was Iso-Aid and the Cesium-131 seeds were manufactured by IsoRay.
(4) What was the model number of the seeds? The model number of the seeds were IAI-125A for the iodine-125 seeds and CS-1 for the cesium-131 seeds.
(5) It was stated that both events occurred due to displacement of the seeds in an inferior direction. Were seed(s) placed in any other organ or tissue (bladder, perineum, etc.)? If so, what were the doses received by those other sites? Preliminary examination seems to indicate that the penile bulb was implanted with some seeds in both cases. Further evaluation is in order to determine the unintended dose to organs surrounding the prostate.

Please change investigation and hiring a medical consultant to “Y”. Due to the nature of the escalated enforcement action, RI management would like to keep this action open because information is still being gathered on questions 2 and 5.