Hospital	Event Number: 44219
Rep Org: VA NATIONAL HEALTH PHYSICS PROGRAM Licensee: VA MEDICAL CENTER, PHILADELPHIA Region: 1 City: PHILADELPHIA State: PA County: License #: 03-23853-01VA Agreement: Y Docket: NRC Notified By: EDWIN LEIDHOLDT HQ OPS Officer: JEFF ROTTON	Notification Date: 05/16/2008 Notification Time: 20:30 [ET] Event Date: 05/05/2008 Event Time: 09:30 [EDT] Last Update Date: 06/21/2008
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE	Person (Organization): PAUL KROHN (R1) HIRONORI PETERSON (R3) REBECCA TADESSEE (FSME)

Event Text

POTENTIAL MEDICAL EVENT DUE TO USE OF I-125 SEEDS OF LOWER APPARENT ACTIVITY THAN INTENDED

"Notification of a possible medical event per 10 CFR 35.3045 - a brachytherapy procedure in which the administered dose may differ from the prescribed dose by more than 0.5 gray to an organ and the total dose delivered may differ from the prescribed dose by twenty percent or more.

"Permittee: VA Medical Center, Philadelphia, PA

"Event: The event occurred on May 5, 2008, and was discovered on May 15, 2008.

"Description: A permanent implant prostate brachytherapy procedure was performed on May 5, 2008, using I-125 seeds. Seeds of a lower apparent activity than intended were mistakenly ordered and implanted. A CT scan of the patient was performed on May 6, 2008, and a postplan was performed on May 15, 2008. The D90 dose, calculated from the postplan, was less than eighty percent of the prescribed dose. Postplans based on CT scans performed approximately one month after an implant, when swelling from the procedure has partially resolved, are believed to provide more accurate assessment of dose to the prostate. It is intended to obtain another CT scan and postplan at about this time to better assess the prostate dose. The permittee intends to make a determination at that time regarding whether a medical event did occur. The permittee will complete a causal analysis and implement procedural changes to prevent a recurrence before any additional brachytherapy procedures are performed.

"Effect on Patients: The VA is continuing to evaluate this event. At this time, adverse effects to the patient are not expected.

"Patient notification: The permittee is ensuring that the referring physicians and patients were notified.

"Licensee will notify the NRC Project Manager, Cassandra Frasier, of NRC Region III."

* * * UPDATE ON 6/06/08 AT 18:16 EDT FROM LEIDHOLDT TO HUFFMAN * * *

"This is an amendment to NRC Event Number 44219 and is a notification of possible medical events per 10 CFR 35.3045.

"The VHA National Health Physics Program notified the NRC Operations Center on May 16, 2008, of

a possible medical event at the VA Medical Center, Philadelphia, Pennsylvania, involving transperineal permanent seed implant prostate brachytherapy.

The VHA National Health Physics Program initiated a reactive inspection on May 28, 2008. As part of this reactive inspection, the medical center was requested to review additional brachytherapy procedures.

Based on a review of other brachytherapy procedures performed between February 1, 2007, and May 31, 2008, the medical center identified an additional four brachytherapy procedures that may be medical events because the D90 doses, determined from post-implant CT scans, were more than 20 percent less than the prescribed doses. The procedures are still under evaluation and a final determination has not been made.

VHA is continuing to evaluate these possible medical events. At this time, adverse effects to the patients are not expected.

If these patient procedures are determined to be medical events, the medical center will ensure that the referring physicians and patients are notified.

VHA has notified NRC, Region III (NRC Project Manager, Cassandra Frasier).

R1DO (Henderson), R3D(Pelke), and FSME (Chang) notified.

A "Medical Event" may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.

* * * UPDATE FROM E. LIEDHOLDT TO JOE O'HARA AT 2009 ON 6/12/08 * * *

"This is an amendment to NRC Event Number 44219 and is a notification per 10 CFR 35.3045 of additional possible medical events.

"VHA notified the NRC Operations Center on May 16, 2008, of a possible medical event at the VA Medical Center, Philadelphia, Pennsylvania, involving transperineal permanent seed implant prostate brachytherapy.

"VHA initiated a reactive inspection on May 28, 2008. As part of this reactive inspection, the medical center was requested to review additional brachytherapy procedures.

"VHA provided an initial update on June 6, 2008. This update reflects the most current information.

"The medical center has identified 45 brachytherapy procedures that could be medical events because the D90 doses, determined from post-implant CT scans, were more than 20 percent less than the prescribed doses. The procedures are still under evaluation and a final determination has not been made.

"We note that the medical center prescribes a dose of 160 gray instead of the more common 145 gray and that the number of possible events would be substantially less if the definition of a medical event were based upon the delivered dose instead of a percent of prescribed dose.

"Furthermore, the medical center determines D90 doses from post-implant CT scans performed the day after the procedures. Prostate swelling may cause the doses assessed from these scans to underestimate the delivered D90 doses.

"The permanent implant brachytherapy program has been suspended by the medical center director and an external review will be performed.

"Effect on patients:

"VHA is continuing to evaluate these possible medical events. At this time, adverse effects to the patients are not expected.

"Patient notification:

"If these patient procedures are determined to be medical events, the medical center will ensure that the referring physicians and patients are notified.

"Other notification:

"VHA has notified NRC, Region III (NRC Project Manager, Cassandra Frasier)."

Notified R1DO(Summers), R3DO(Louden), and FSME(Mauer).

* * * UPDATE BY E. LEIDTHOLDT TO J. KOZAL ON 6/21/08 AT 1841 * * *

"This is an amendment to NRC Event Number 44219, reported on May 16, 2008, and is a notification per 10 CFR 35.3045 of additional possible medical events. VHA provided amendments on June 6 and 12, 2008. This amendment reflects the most current information.

"VHA notified the NRC Operations Center on May 16, 2008, of a possible medical event at the VA Medical Center, Philadelphia, Pennsylvania, involving a transperineal permanent seed implant prostate brachytherapy procedure of a patient. This patient procedure is now considered to be a medical event.

"VHA initiated a reactive inspection on May 28, 2008. As part of this reactive inspection, the medical center was requested to review additional prostate brachytherapy procedures.

"The medical center has identified 63 brachytherapy procedures that could be medical events because the D90 doses, determined from post-implant CT scans, were 80% or less than the prescribed doses. The procedures are still under evaluation and a final determination has not been made for 60 of these procedures. For three of these 63 procedures including the May 5, 2008, procedure, the D90 doses have been confirmed to be 80% or less than the prescribed doses.

"We note that the medical center routinely prescribes a dose of 160 gray instead of the more common 145 gray and that the number of possible events would be substantially less if the definition of a medical event were based upon the delivered dose instead of a percent of prescribed dose.

"Furthermore, the medical center determines D90 doses from post-implant CT scans performed the day after the procedures. Prostate swelling may cause the doses assessed from these scans to underestimate the delivered D90 doses.

"The permanent implant brachytherapy program is suspended and an external review is in progress.

"Effect on patients:

"VHA is continuing to evaluate these possible medical events. At this time, adverse effects to the patients are not expected. The external review will assess potential medical consequences.

"Patient notification:

"The three patients whose D90 doses were confirmed to be 80% or less than the prescribed doses and their referring physicians have been notified. If other patient procedures are determined to be medical events, the medical center will ensure that the referring physicians and patients are notified.

"Other notification:

"VHA will notify NRC, Region III (NRC Project Manager, Cassandra Frasier)."

Notified R1DO (Schmidt), R3DO (Kunowski), and FSME (Holonich)