

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: 08/12/2009
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)

* * * UPDATE PROVIDED BY THOMAS HUSTON TO JASON KOZAL AT 1758 ON 6/25/08 * * *

"This report is an update to Event Report #44219. As the result of an ongoing review, a medical event was discovered for a fourth patient on June 24, 2008. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of the event will be sent to NRC Region III."

Notified R1DO (Grey), R3DO (Burgess), and FSME EO (Camper).

* * * UPDATE PROVIDED BY THOMAS HUSTON TO JOHN KNOKE AT 1245 ON 07/02/08 * * *

"This report is an update to Event Report #44219. As the result of an ongoing review, medical events were discovered for an additional seven (7) patients on July 2, 2008. This brings the total number of medical events to eleven (11) under Event

Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these seven (7) additional medical events will be submitted to NRC Region III."

Notified R1DO (Bellamy), R3DO (Kozak), and FSME EO (Zelac).

* * * UPDATE FROM HUSTON TO CROUCH ON 07/08/08 AT 1319 EDT * * *

"As the result of an ongoing review, medical events were discovered for an additional seven (7) patients on July 7, 2008. This brings the total number of medical events to eighteen (18) under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these seven (7) additional medical events will be submitted to NRC Region III."

Notified R1DO (Burritt), R3DO (Duncan) and FSME EO (Burgess).

* * * UPDATE PROVIDED BY LYNN MCGUIRE TO JOHN KNOKE AT 1335 ON 07/09/08 * * *

A 15-day written report of one of the medical events was submitted to NRC Region III.

Notified R1DO (Burritt), R3DO (Duncan) and FSME EO (Burgess).

* * * UPDATE FROM THOMAS HUSTON TO JOE O'HARA AT 0943 ON 7/10/09 * * *

"This report is an update to Event Report #44219. As the result of an ongoing review, medical events were discovered for an additional two (2) patients on July 9, 2008. This brings the total number of medical events to twenty (20) under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these two (2) additional medical events will be submitted to NRC Region III.

"We have notified our NRC Project Manager, Cassandra Frazier (NRC Region III), of these additional events."

Notified R1DO(Burritt), R3DO(Duncan), and FSME EO(Burgess)

* * * UPDATE ON 7/15/2008 AT 1213 FROM GARY WILLIAMS TO MARK ABRAMOVITZ * * *

"This report is an update to Event Report #44219. As the result of an ongoing review, medical events were discovered for an additional nine patients on July 15, 2008. This brings the total number of medical events to 29 under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these nine additional medical events will be submitted to NRC Region III. I will notify our NRC Project Manager, Cassandra Frazier (NRC Region III), of these additional events."

Notified R1DO (Dentel), R3DO (Lara), and FSME (Burgess).

* * * UPDATE ON 7/18/2008 AT 1313 FROM HUSTON TO HUFFMAN * * *

"This report is an update to Event Report #44219. As the result of an ongoing review, medical events were discovered for an additional three patients on July 18, 2008. This brings the total number of medical events to 32 under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these three additional medical events will be submitted to NRC Region III. We will notify our NRC Project Manager, Cassandra Frazier (NRC Region III), of these additional events. "

Notified R1DO (Dentel), R3DO (Lara), and FSME (White).

* * * UPDATE ON 7/22/2008 AT 1500 EDT FROM WILLIAMS TO HUFFMAN * * *

"This report is an update to Event Report #44219. As the result of an ongoing review, medical events were discovered for an additional five patients on July 22, 2008. This brings the total number of medical events to 37 under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these

five additional medical events will be submitted to NRC Region III."

The licensee will notify NRC Project Manager, Cassandra Frazier (NRC Region III), of these additional events.

Notified R1DO (Dentel), R3DO (Riemer), and FSME (Burgess).

* * * UPDATE FROM GARY WILLIAMS TO JOE O'HARA 1145 EDT ON 7/25/08 * * *

"As the result of an ongoing review, medical events were discovered for an additional two patients on July 25, 2008. This brings the total number of medical events to 39 under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these two additional medical events will be submitted to NRC Region III. Our NRC Project Manager, Cassandra Frazier (NRC Region III), is aware of these additional events."

Notified R1DO (W.Cook), R3DO (M.Phillips), and FSME (C.Flannery)

* * * UPDATE AT 0805 ON 08/06/08 FROM THOMAS HUSTON TO JEFF ROTTON * * *

"As the result of an ongoing review, medical events were discovered for an additional four patients on August 05, 2008. This brings the total number of medical events to 43 under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these five additional medical events will be submitted to NRC Region III. Our NRC Project Manager, Cassandra Frazier (NRC Region III), is aware of these additional events."

Notified R1DO (Gray), R3DO (D.Hills), and FSME (C. Einberg)

* * * UPDATE AT 1002 EDT ON 8/13/08 FROM HUSTON TO SANDIN * * *

"This report is an update to Event Report #44219. As the result of an ongoing review, medical events were discovered for an additional four patients on August 12, 2008. This brings the total number of medical events to 47 under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these four additional medical events will be submitted to NRC Region III. I will notify our NRC Project Manager, Cassandra Frazier (NRC Region III), of these additional events."

Notified R1DO (Holody), R3DO (Kozak) and FSME (Burgess).

* * * UPDATE AT 1422 EDT ON 8/22/08 FROM HUSTON TO KNOKE * * *

"This report is an update to Event Report #44219. As the result of an ongoing review, medical events were discovered for an additional eight patients on August 21, 2008. This brings the total number of medical events to 55 under Event Report #44219. The circumstances involved are similar to those previously reported for this event number. A 15-day written report of these four additional medical events will be submitted to NRC Region III. We will notify our NRC Project Manager, Cassandra Frazier (NRC Region III), of these additional events."

Notified by email: R1DO (Perry), R3DO (Lipa) and FSME (Burgess).

* * * UPDATE AT 1704 ON 10/2/2008 FROM THOMAS HUSTON TO MARK ABRAMOVITZ * * *

"As the result of an ongoing reviews, medical events were discovered for an additional 37 patients on October 1, 2008. This brings the total number of medical events to 92 under Event Report #44219.

"The circumstances are related to those previously reported for this event number with the following clarifications:

- 35 of the additional medical events involve doses to organs or tissues other than the treatment site and are considered to meet medical event criteria described in 10 CFR 35.3045(a)(3).
- 2 of the additional medical events involve doses to the treatment site (prostate) that had a D90 dose below 80% of the prescribed dose.
- These 37 additional medical events involve different patient cases that have not been previously reported as medical events under this event report.

"A 15-day written report of these 37 additional medical events will be submitted to NRC Region III.

"We informed our NRC Project Manager, Cassandra Frazier (NRC Region III), of the additional events."

Notified R1DO (White), R3DO (Lara), and FSME (Bradford).

* * * UPDATE PROVIDED BY EDWIN M. LEIDHOLDT, JR TO JASON KOZAL ON 08/12/09 AT 1820 * * *

"Event Report No. 44219 documents the VA's notification of the NRC of medical events involving permanent implant prostate brachytherapy at the Philadelphia VA Medical Center, beginning with a notification on May 16, 2009. As a result of ongoing reviews, the NHPP is notifying NRC of six additional medical events at the Philadelphia VA Medical Center. These events, also involving prostate brachytherapy with I-125 seeds, were discovered on August 12, 2009. These additional six medical events involve D90 doses less than 80% of the prescribed dose.

"The D90 doses for all six events reported today were based upon CT scans performed one day after each implant, when the prostate is subject to edema from the procedure which often causes underestimation of the true D90. Furthermore, the prescribed doses were 160 gray, instead of the more common 145 gray. Most if not all of these six patients likely received clinically adequate dose distributions, despite the percent-wise slightly low D90s. Adverse biological effects to these six patients are not expected. We are reporting these six additional events to meet a regulatory requirement, not because of any anticipated harm to these patients.

"The facility is aware of the requirement to notify the patients.

"A written report on these additional medical events will be submitted to NRC Region III pursuant to 10 CFR 35.3045. We will notify the NRC Project Manager, Cassandra Frazier, of NRC Region III."

Notified R1DO (Cook), R3DO (Cameron), and FSME EO (Mauer).