



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

JUL 08 2008

In Reply Refer To: 598/115HP/NLR

Cassandra F. Frazier
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA

Dear Ms. Frazier,

I am forwarding the enclosed report regarding Event Number 44219. The report addresses a medical event that occurred at the VA Medical Center, Philadelphia, Pennsylvania, and is submitted pursuant to 10 CFR 35.3045(d). The medical center holds VHA Permit Number 37-00062-07 under our master material license.

A medical event involving a single patient occurred on March 6, 2006, was discovered by the medical center on June 24, 2008, and was reported to the NRC Operations Center on June 25, 2008. The event involved permanent implant prostate seed brachytherapy.

My staff performed the initial on-site part of a reactive inspection on May 28-29, 2008, and returned on June 24-25, 2008, to evaluate the circumstances of the events, assess initial actions to prevent a recurrence, and assess regulatory compliance. This inspection remains open. At the exit meeting on May 29, 2008, the inspectors asked the medical center to review a sample of additional brachytherapy treatments. This review by the medical center has revealed additional patient procedures that might be medical events. The NRC Operations Center was notified of these additional possible medical events on June 6, 12, and 21, 2008, as amendments to Event Number 44219. This report addresses one of these additional possible medical events.

If you have any questions, please contact me at (501) 257-1571.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Lynn McGuire".

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

RECEIVED JUL 15 2008



PHILADELPHIA

VA MEDICAL CENTER

3900 Woodland Avenue, Philadelphia, PA 19104
(215) 823-5800

Official Fax Transmittal

To: <i>LISA OFFUTT</i>	Fax #: <i>501-257-1570</i>
	Phone #: <i>501-257-1574</i>

From: <i>MARY MOORE</i>	Fax #: <i>215-823-6009</i>
	Phone #: <i>215-823-4424</i>

Subject: <i>Brachy Med Event - Patients H-F</i>

Date:	No. of Pages: (incl. cover sheet)
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Description: <i>Matrix updates to follow</i> <i>Mary</i>

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Potential Medical Event - NRC Number 44219**Notification of a possible medical event per 10 CFR 35.3045:**

A brachytherapy procedure in which the administered dose may differ from the prescribe dose by more than 0.5 gray to an organ and the total dose delivered may differ from the prescribed dose by 20% or more.

VA Master Materials License **NRC License No. 03-23853-01VA**

Permittee: VA Medical Center, Philadelphia, PA

Date of Event: March 6, 2006

Date Discovered: June 24, 2008

Date Reported to NHPP: June 24, 2008

Date Reported to NRC: June 25, 2008

Name of Prescribing Physician: Gary Kao, M.D.

Description of the Event:

A permanent prostate brachytherapy implant procedure was performed on March 6, 2006 using I-125 seeds. The activity per seed and number of seeds prescribed in the written directive and used in the treatment plan were ordered, received and implanted. The original post-treatment plan was performed on May 30, 2006 and was based on the CT scan performed on March 7, 2006. The D90 dose was significantly lower (more than -20%) than the planned D90 dose to the prostate. As per the nomogram shared with NHPP, VACO, and Dr Giri, Chief, National VA Radiation Oncology Program, current medical events are confirmed based on repeat CT scans since the original prostate dose was based on Day-1 post-procedure CT scans. As a result this patient was contacted to obtain a current CT. Using the June 18, 2008 CT scan, the prostate was re-contoured on 6-20-08 and a post-treatment plan was run on 6-24-08. The updated D90 was lower than the previous May 30, 2006 results. The RSO and Chief of Radiation Oncology Service reviewed these results and determined a Medical Event had occurred. At approximately 4:15 pm on 6-24-08, the RSO informed NHPP of these findings. This patient's data is being reviewed as part of the causal analysis currently in process. Any necessary procedural changes will be implemented to prevent a recurrence before any additional brachytherapy procedures are performed. The brachytherapy program was formally put on-hold in early June, 2008/

Why the Event Occurred:

Root causes of event are still under investigation.

Effect on Patient:

Effect on patient is still under review.

Possible Medical Event NRC Event No. 44219

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Corrective Actions:

- Program is on -hold pending results of investigation
- QA program for Radiation Oncology is under review

Patient notification:

On 6-25-08 the Chief of Radiation Oncology Service phoned the patient and referring physician and Physician Assistant to inform them of the lower than planned prostate dose. The patient was informed that his prostate received a dose much lower than planned. He was advised to have a PSA test performed before his follow-up appointment in September, and that he was entitled to receive a written report of the event.



**Department of
Veterans Affairs**

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Little Rock, Arkansas 72205-5484

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