



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

AUG 19 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 four medical events 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.

Four medical events were reported to the NRC Operations Center on August 6, 2008. The events involved permanent implant prostate seed brachytherapy.

My staff performed the initial on-site part of a reactive inspection May 28-29, 2008, and returned June 24-25, 2008, to evaluate the circumstances of related 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 is ongoing and has revealed additional patient procedures that meet the definition of a medical event. The NRC Operations Center was notified of these additional medical events on June 6, 12, 21, 25; July 2, 8, 10, 15, 18, 22, 25; and August 6, 2008. The additional events were recorded by the NRC Operations Center as updates to Event Number 44219. This report addresses the additional medical events reported to NRC on August 6, 2008.

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

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Potential Medical Event - NRC Number 44219 Addendum

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 20% or more.

VA Master Materials License **NRC License No. 03-23853-01VA**
Permittee: VA Medical Center, Philadelphia, PA
Date(s) of Event(s): See IMPLANT DATES below
Date Discovered: August 5, 2008: Four events found
Date Reported to NHPP: August 5, 2008: Four events found
Date Reported to NRC: August 6, 2008
Name of Prescribing Physician: Gary Kao, M.D., Ph.D.

<u>Patient XRT #</u>	<u>Implant Date</u>	<u>Original CT Date</u>	<u># Seeds Recovered</u>	<u>Original Post Plan</u>	<u>Repeat CT</u>	<u>Re-Contour Date</u>	<u>Repeat Rx Plan</u>
020	2-25-02	2-26-02	3	2-26-02	7-16-08	7-25-08	7-31-08
037	10-31-05	11-1-05	0	11-14-05	7-20-08	7-25-08	7-31-08
082	1-8-07	1-9-07	0	11-30-07	7-18-08	7-25-08	7-31-08
091	3-27-06	3-28-06	2	4-3-06	7-16-08	7-25-08	7-31-08

Description of the Event:

Permanent prostate brachytherapy implant procedures were performed using Iodine-125 seeds on the dates listed above. The activity per seed and number of seeds prescribed in the written directives and used in the original treatment plans were ordered, received and implanted. The original post-treatment plans for the above patients were based on CT scans obtained the day after the Implant Date. The D90 prostate doses for the above 4 patients were significantly lower (e.g. more than 20%) than the planned prostate D90 dose. These patients' implants are under review to determine cause(s) of doses being more than 20% lower than the prescribed dose

As per the nomogram shared with NHPP, VACO, and Dr Giri, Chief, National VA Radiation Oncology Program, the above medical events are confirmed based on recently obtained repeat CT scans since the original prostate dose was based on Day-1 post-procedure CT scan. As a result these patients were contacted to obtain a current CT. Using the Repeat CT scans

for each patient listed above, the prostates were re-contoured and additional post-treatment plans were run on the respective dates listed above. The updated D90s were less than 80% of the original planned intended D90 prostate dose.

On August 5, 2008, the RSO and Chief of Radiation Oncology Service completed their review of the results for the above patients and determined Medical Events had occurred. On August 5, 2008, the RSO notified NHPP of these findings. The data for these patients 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, and remains on-hold.

Why the Event Occurred:

Currently causal review is still in progress and thus no final determinations as to causality can be concluded. Causal analysis is a charge to the Administrative Board of Investigation (ABOI) that is in process. All external review has been subsumed by and into the ABOI per the PVAMC Director. Final recommendations and completion of the review of the Internal Review Team are pending review of other bodies.

Preliminary observations by the Internal Review Team that require validation and further input include the following:

- Lack of proper local Quality Control and Management of brachytherapy program
- Lack of policies to address post-implant management of patients and patient dosing
- Interruption of connectivity between radiation oncology and radiology for a period of approximately 1 year: This contributed to the inability to calculate patient doses during this time frame, but it was not causative for doses being outside of accepted range

Effect on Patient:

Effect on patients is still under review. Patients are being followed using established medical criteria (e.g. PSA) to evaluate possible effects of under-dosing which could include treatment failure. If it appears treatment failure is occurring, patient records are being reviewed by independent experts to obtain possible treatment options which will be offered to the patient. Each case is being individually reviewed to determine if additional treatment is indicated and what specific modality would be most efficacious with respect to clinical condition, PSA levels and initial dosing.

Corrective Actions:

- Program was placed on-hold in early June, 2008 and remains in that status pending results of on-going investigation
- A QM program has been implemented in Radiation Oncology.
- Re-education regarding Medical Events has been, and is being, provided to Radiation Oncology, Nuclear Medicine, Radiation Safety Committee members and other staff. This is an ongoing process.
- Communication barriers between Radiation Oncology staff have been reviewed and removed.

Patient notification:

On August 5 and 6, 2008, the Chief of Radiation Oncology Service phoned the above patients and their referring physicians/ primary care providers. Patients and their referring physicians, and/or primary care providers, were informed the patients received a lower than planned prostate dose, that the patients cases were being reviewed externally by an expert to obtain treatment option recommendations, and that the patients were entitled to receive a written report of the event.

From: Origin ID: LITA (501) 257-1571
Kelly Mayo
VHA National Health Physics Pr
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NORTH LITTLE ROCK, AR 72114



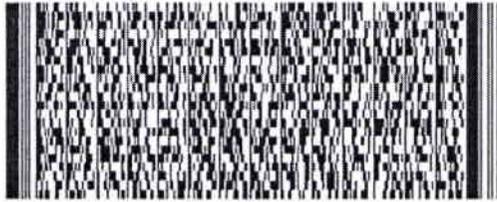
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SHIP TO: (501) 257-1571 **BILL SENDER**
Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532

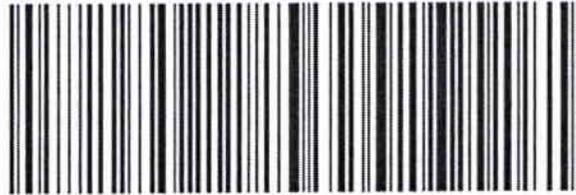


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