



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

AUG 26 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 13, 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 and 13, 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 13, 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

Possible Medical Event **NRC Event No. 44219**

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August 12, 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:

1. Program was placed on-hold in early June 2008 and remains in that status pending results of on-going investigation.
2. Institution of local QC/QM program in Radiation Oncology was established as of July 27 and is on-going.
3. In July 2008, Radiation Safety Committee initiated requirement for and review of QC programs in Nuclear Medicine, Radiology, Dental and Cardiology in addition to Radiation Oncology.
4. Complete policy review of brachytherapy and development of new policies to address pre and post-implant care; final recommendations are pending the outcome of on-going investigation.
5. Training Radiation Oncology staff in radiation safety procedures, and in particular the definition and recognition of a medical event and PVAMC Open Door Policy, is in process and is instituted as an ongoing process. Re-training Nuclear Medicine staff and Radiation Safety Committee members about Medical Events has been implemented.

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6. Review of procedure to determine the optimal timing of post-implant CT scans (1 day versus 30 day) and to determine the logistics in obtaining such CT scans. Final process policies will be instituted based on the format of brachytherapy in the future as to whether this program will be either "real-time" or whether implants will be performed in the OR as per present protocol.

Patient notification:

On August 13, 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.