



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

**JUL 21 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 seven 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.

A medical event involving seven patients was reported to the NRC Operations Center on July 8, 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, 21, 25, and July 2, 8, 10, 15, and 18, 2008, as amendments to Event Number 44219. This report addresses seven 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



Possible Medical Event                      NRC Event No. 44219

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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 July 7, 2008, the RSO and Chief of Radiation Oncology Service reviewed the results for the above patients and determined Medical Events had occurred. On 7-8-08, 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.

**Why the Event Occurred:**

Root causes of event are still under investigation.

**Effect on Patient:**

Effect on patient is still under review.

**Corrective Actions:**

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

**Patient notification:**

On July 8, 2008, the Chief of Radiation Oncology Service phoned the above 7 patients and their referring physicians/ primary care providers. Five of the 7 patients were reached by phone on July 8 and messages requesting them to return the call were left for 2 patients. One patient returned the call on July 9<sup>th</sup> and a second patient returned the call on July 10, 2008. Patients and referring physicians, and/or primary care providers, were informed the patients received a lower than planned prostate dose, 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.