



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

**JUL 30 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 nine 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 nine patients was reported to the NRC Operations Center on July 15, 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, 18, 22, and July 25, 2008, as amendments to Event Number 44219. This report addresses nine 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 31 2008

**Potential Medical Event - NRC Event 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:**                            July 15, 2008: Nine events found

**Date Reported to NHPP:**                    July 15, 2008: Nine events reported

**Date Reported to NRC:**                     July 15, 2008

**Name of Prescribing Physician:**        Gary Kao, M.D., Ph.D.  
     Richard Whittington, M.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>
002 *	9-16-02	9-17-02	4 not used	9-20-02	7-8-08	7-11-08	7-14-08
010	6-12-06	6-13-06	0	6-14-06 8-2-06	7-9-08	7-11-08	7-14-08
027	1-14-08	1-15-08	1	1-22-08 5-21-08	7-3-08	7-11-08	7-14-08
056	2-23-04	2-24-04	0	3-5-04	7-3-08	7-11-08	7-14-08
064	10-7-02	10-8-02	2	10-9-02 8-2-06	7-8-08	7-11-08	7-14-08
076	11-20-06	11-21-06	0	Not in chart	2-19-08	7-3-08	7-13-08
087	1-24-05	1-25-05	0	1-25-05 2-9-05	7-8-08	7-11-08	7-14-08
108	7-17-06	7-18-06	1	7-21-06	6-26-08	7-3-08	7-13-08
109	6-14-04	6-15-04	0	8-23-04	6-26-08	7-3-08	7-13-08

**Description of the Event:**

Nine 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 a CT scan obtained the day after the Implant Date. One patient's post-treatment plan was not in his chart. The D90 doses to the prostate for the above patients were significantly lower (more than -20%) than the prescribed dose.

As per the nomogram shared with NHPP, VACO, and, 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 prescribed prostate dose.

On July 15, 2008, the RSO and Chief of Radiation Oncology Service reviewed the results for the above patients and determined Medical Events had occurred. On 7-15-08, 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:**

Effects on patients are 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 15, 2008, the Chief of Radiation Oncology Service phoned 8 of the above 9 patients and their referring physicians/ primary care providers. The other patient was contacted by the radiation oncologist noted above by the "\*" also on 7-15-08. 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 written reports of the events.

From: Origin ID: LITA (501) 257-1571  
 Kelly Mayo  
 VHA National Health Physics Pr  
 2200 FORT ROOTS DR  
 B101 R208E  
 NORTH LITTLE ROCK, AR 72114



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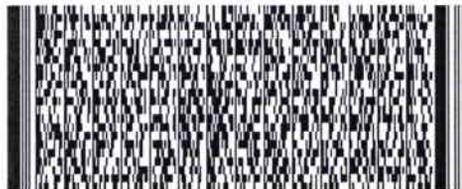
SHIP TO: (501) 257-1571 BILL SENDER

**Cassandra Frazier**  
**Nuclear Regulatory Commission**  
**2443 Warrenville Road**  
**Suite 210**  
**Lisle, IL 60532**

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