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

AUG 26 2009

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,

We are forwarding the enclosed written report regarding NRC Event Number 44219. The report addresses six 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. These medical events were reported to the NRC Operations Center on August 12, 2009. The events involved permanent implant prostate seed brachytherapy.

These six events are related to medical events declared for this facility beginning in May of 2008. We performed a reactive inspection of related medical events at the facility beginning May 28, 2008, and continuing until October 3, 2008. We are in the process of conducting an on-site visit at the facility on August 26-27, 2009, as part of an open inspection to evaluate details of these six events, as well as revised dose data for all earlier events reported under NRC Event Number 44219.

We note that on August 6, 2009, the facility provided revised dose data to our office for all 114 treatments. Doses had been re-evaluated by the facility using the CT scans performed one day after treatment. We forwarded that data to your office by e-mail on August 7, 2009. We then evaluated the data, and on August 12, 2009, we concluded that six of the treatments had a revised D90 (to prostate) less than 80% of the dose prescribed in the written directive. These six cases were not reported as medical events earlier (i.e., during 2008) because the earlier D90s, based on CTs performed during 2008, were greater than 80% of the prescribed dose. The facility subsequently decided that the day-one CT is more valid than the later CTs for determining medical events.

Sincerely,

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

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Enclosure

NRC Licensee: Dept. of Veterans Affairs, Veterans Health Administration

NRC License Number: 03-23853-01VA

VHA Permittee: VA Medical Center, Philadelphia, Pennsylvania (PVAMC)

VHA Permit Number: 37-00062-07

Prescribing Physicians: Gary Kao, M.D., Ph.D.
Richard Whittington, M.D.

Summary Information for Medical Events Discovered/Reported August 12, 2009

Patient Reference	Implant Date	Prescribing Physician	Prescribed Dose (Gy)	D90 (per Day-1 CT) (Gy)**	% of Prescribed (Day-1 CT)	D90 (per 2008 CT) (Gy)	% of Prescribed (2008 CT)
XRT 059	1/12/2004	GK	160	118	74%	142	89%
XRT 061*	4/11/2005	GK	160	123	77%	147	92%
XRT 069	8/30/2004	RW	160	110	69%	130	81%
XRT 081	1/31/2005	GK	160	109	68%	169	106%
XRT 083	2/7/2005	GK	160	124	78%	186	116%
XRT 110	9/13/2004	GK	160	121	76%	148	93%

GK = Gary Kao, M.D., Ph.D.
RW = Richard Whittington, M.D.

***Note for Patient XRT 061** – This identification number was incorrectly typed in the written report dated August 7, 2008, for medical events (reported to NRC Operations Center July 25, 2008) and submitted by NHPP to the NRC. **The correct XRT number for the August 7, 2008, written report is XRT # 62.**

**D90 values are based on original contours using Day-1 CT except for Patients XRT 069 and 083, which are based on re-countered Day-1 CTs.

Description of the Events:

These six medical events were associated with permanent implant prostate seed brachytherapy at PVAMC. The original medical event criteria used by the permittee to determine if a medical event had occurred was based on CT scans obtained between June and August 2008. Review of the CT scans performed at times temporally distant from the original procedure (greater than 6 months) found significant seed migration and tissue changes that preclude continued use of the 2008 CT scans as the basis for determining medical events. The 2008 CT scans are not representative of the original treatments. While seed migration and tissue changes post treatment have been reported in the medical literature, the extent of these changes exceeded expectations. As such, the original Day-1 CT results for the above patients are being used for this report. The original physician contour, or the re-contoured original CT by an independent physician, has been used for this report.

During the review of the above patients, PVAMC noted that, based on the Day-1 CT, the percentage of seeds (or activity) in the Designated Treatment Site (DTS) was significantly greater than 80%; however, the D90s to the prostate were not greater than 80%. The written directive prescribed a dose in gray. For purposes of this retrospective review, the VHA National Health Physics Program (NHPP), in concurrence with the VA National Radiation Safety Committee (NRSC), has specified that any patient with a D90 less than 80% is to be identified as

a medical event. PVAMC provided NHPP with revised D90 values on August 6, 2009, for all 114 patient treatments performed by its program. NHPP evaluated the data on August 12, 2009, and concluded on that date that these six treatments were medical events per 10 CFR 35.3045(a)(1) -- total dose to the treatment site (as quantified using D90 to prostate) was greater than 20% below the prescribed dose. NHPP notified staff at PVAMC and the NRC Operations Center of the six medical events on August 12, 2009.

Why the Events Occurred:

Medical events involving the prostate brachytherapy program at PVAMC have been, and are being, reviewed both internally by a VA Administrative Board of Inquiry, by the VA National Patient Safety Office, NHPP, and VA Office of Inspector General, as well as externally by the Nuclear Regulatory Commission. The findings of the VA groups include the following causes:

- Lack of proper clinical quality control and management of the brachytherapy program
- Lack of adequate policies to ensure post-implant management of patients and patient dose
- Lack of assurance that contractual specifications between PVAMC and the affiliate were being fulfilled
- Inadequate supervision of Radiation Oncology staff by PVAMC and the University of Pennsylvania affiliate who provided contracted services
- Lack of program oversight with inadequate review surrounding past trigger events relating in part to lack of policies to address programmatic review
- Lack of effective safety culture

Effects on Patients:

To date, there have been no deterministic radiation effects reported for the six patients listed above. Their clinical conditions remain acceptable and stable. No adverse effects are expected for these six patients. All prostate brachytherapy patients treated at PVAMC are being followed clinically, either at PVAMC or at their local VA facility if patients live more than a two-hour drive from Philadelphia. Long-term effects are being evaluated and clinical follow-ups will continue indefinitely for all patients. Patients who would benefit from a second boost implant were offered that option; however, none of these six patients needed a second boost implant.

Corrective Actions:

PVAMC self-initiated suspending the program in June 2008 until a full evaluation could be completed. That evaluation is still in process. No prostate brachytherapy procedures have been performed at PVAMC since June 2, 2008. PVAMC policies and procedures have been revised. Extensive radiation safety training has occurred that included, but was not limited to, definition and recognition of a Medical Event, culture of safety, and notification requirements. Efforts to improve communication between PVAMC and its affiliate are in process. Before PVAMC could restart a prostate brachytherapy program, it will be required to implement the new VHA standard procedures for prostate brachytherapy programs, request inspection by NHPP, and obtain approval by VHA. At this time, PVAMC has no plans to restart the prostate brachytherapy program.

Patient/Referring Physician Notifications:

The six patients and their referring physician were notified in compliance with 10 CFR 35.3045. NHPP declared these treatments as medical events on August 12, 2009. The referring physician for the six patients was the Chief of Urology Service at PVAMC; he was notified about the new status designated by NHPP. In addition, the Chief of Radiation Oncology at PVAMC called the respective primary care providers for each of these patients to ensure they receive the follow-up needed.

On August 13, 2008, PVAMC Radiation Oncology staff phoned all six patients. They reached and informed five patients of their medical event status based on revised D90 values. The sixth patient could not be reached until August 15 and was informed of medical event status on August 17, as noted below. All patients were informed that they were entitled to request and receive a written description of the event.

Summary of Patient Notifications:

- Patient XRT 059 was called on August 13, 2009, at 12:30 pm and a voice message was left requesting that the patient call the hospital. On August 14, 2009, a second call was made but there was no answer. A voice message was left requesting a call back. On August 14, 2009, at 1:30 pm, the hospital Federal Expressed a "next day delivery" letter to this patient. On August 15, 2009, the patient picked up the letter. The patient called Radiation Oncology on August 17, 2009, and received the updated information.
- Patient XRT 061 was called and informed on 8/13/09 at 10:15am.
- Patient XRT 069 was called and informed on 8/13/09 at 11:00 am.
- Patient XRT 081 was called and informed on 8/13/09 at 10:00 am.
- Patient XRT 083 was called and informed on 8/13/09 at 11:00 am.
- Patient XRT 110 was called and informed on 8/13/09 at 10:45 am.

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

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