VHA National Health Physics Program (115HP/NLR)
2200 Fort Roots Drive, Building 101, Room 208D
North Little Rock, Arkansas 72114
501-257-1571
Fax: 501-257-1570

FAX

To: Cassandra Frazier, MML Project Manager **From:** Ed Leidholdt

Fax Number: 630-515-1078 **Pages:** Four, including this sheet

Subject: Philadelphia medical event **Date:** 21 June 2008

Comments: E-mail copy to follow.

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

JUN 2 1 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 medical events and possible 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 possible medical event involving a single patient occurred on May 5, 2008, was discovered by the medical center on May 15, 2008, and was reported to the NRC Operations Center on May 16, 2008. A report, dated May 30, 2008, on this event was submitted to NRC Region III pursuant to 10 CFR 35.3045(d). The event involved permanent implant prostate seed brachytherapy. The facility has subsequently determined this to be a medical event.

My staff performed the initial on-site part of a reactive inspection on May 28-29, 2008, to evaluate the circumstances of the event, 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, and 21, 2008, as amendments to Event Number 44219. This report addresses these additional possible medical events.

If you have any questions, please contact me at (501) 257-1571.

Sincerely,

P. Lathbold for

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

Medical Events and Possible Medical Events – NRC Event Report No. 44219

Licensee's Name:

US Department of Veterans Affairs, NRC License 03-23853-01VA

Permittee's Name:

VA Medical Center, Philadelphia, Pennsylvania, VHA Permit Number 37-00062-07

Names of the prescribing physicians:

Gary Kao, M.D.
Richard Whittington, M.D.

Brief description of the events:

The medical center performs permanent implant seed brachytherapy of the prostate gland using iodine-125 seeds. A possible medical event involving a single patient occurred on May 5, 2008, was discovered by the medical center on May 15, 2008, and was reported to the NRC Operations Center on May 16, 2008. The D90 dose to this patient, calculated from a CT study performed the day after the implant procedure, was much less than 80 percent of the prescribed dose. This event was described in a report, dated May 30, 2008, submitted to NRC Region III pursuant to 10 CFR 35.3045 (d). One cause of this event was that the activities of the seeds that were ordered from a vendor and implanted in the patient were of significantly lower apparent activity than the activity specified in the treatment plan and seed loading diagrams. D90 doses, assessed immediately after a procedure, may underestimate actual D90 doses because of prostate edema from the procedure. A repeat CT scan was performed on June 4, 2008, and another postplan was obtained. The D90 dose from this postplan is also much less than 80 percent of the prescribed dose and the medical center has determined that this procedure constituted a medical event as defined in 10 CFR 35.3045.

The VHA National Health Physics Program (NHPP) performed the initial on-site part of a reactive inspection on May 28-29, 2008, to evaluate the circumstances of the possible medical event, assess initial actions to prevent a recurrence, and assess regulatory compliance. This inspection remains open. At an exit meeting on May 29, 2008, the inspectors asked the medical center to review a sample of additional brachytherapy treatments and provide that information.

On June 5, 2008, the medical center completed a review of the postplans of an additional 19 patients and found several that might meet the definition of a medical event because the D90 doses, determined from CT scans performed the day after the implant procedures, were 80% or less than the prescribed doses. The medical center notified the NHPP of additional possible medical events and the NHPP notified the NRC Operations Center on June 6, 2008.

The medical center extended the review to another 50 patient procedures, for a total of 70 procedures. This review was completed on June 11, 2008. For 45 of the 70 procedures, the D90 doses, based upon CT scans performed the day after the implant procedures, were 80% or less than the prescribed doses. The Medical Center Director ordered a suspension of prostate brachytherapy procedures and an external review of the prostate brachytherapy program. No patient implant procedures were performed after June 2, 2008. The medical center notified the

NHPP of the additional possible medical events and the NHPP notified the NRC Operations Center on June 12, 2008. On that date, 44 procedures were considered possible medical events and the procedure performed on May 5, 2008, was considered to be a medical event.

On June 20, 2008, the medical center notified the NHPP that two additional procedures, among the 44 being reviewed as possible medical events, were determined to be medical events based upon the criteria of a D90 dose equal to or less than 80% of the prescribed dose. Thus, at this time, a total of three procedures are considered to be medical events. The medical center also notified the NHPP that the review has been extended to 102 patient procedures. The D90 doses of 60, in addition to the 3 determined to be medical events, were 80% or less than the prescribed doses.

Why the events occurred:

The causes of the events and possible events, other than the one occurring on May 5, 2008, have not yet been determined. Some of the causes of the event occurring on May 5, 2008, have been determined and were stated in our report dated May 30, 2008.

The effect, if any, on the individuals who received the administrations:

The effects on the individuals are under review by the medical center.

What actions, if any, have been taken or are planned to prevent a recurrence:

The Medical Center Director has suspended permanent implant prostate seed brachytherapy until an external review, involving a radiation oncology physician and a medical physicist with expertise in prostate seed brachytherapy, is performed; a causal analysis is performed; and actions to prevent a recurrence are implemented. All patient procedures since the inception of the prostate seed brachytherapy program are being reviewed.

Certification that the licensee notified the individuals:

The permittee has notified the patient whose procedure was performed on May 5, 2008, and the other two patients whose D90 doses were confirmed to be 80% or less than the prescribed doses. The patient procedures designated as possible medical events are under review. If any of these patient procedures under review are determined to be medical events, the individuals will be notified pursuant to NRC regulations and VA requirements.