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

MAY 30 2008

In Reply Refer To: 598/115HP/NLR

Cassandra F. Frazier
Division of Nuclear Material Safety
Nuclear Regulatory Commission (NRC), 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 medical event report for Event Number 44219. The report is in the format of a letter from the VA Medical Center, Philadelphia, Pennsylvania, that is dated May 28, 2008. The medical center holds VHA Permit Number 37-00062-07 under our master materials license.

The report is submitted per 10 CFR 35.3045(d) for a possible medical event which occurred on May 5, 2008, at the medical center. The event was discovered on May 15, 2008, and reported to the NRC Operations Center on May 16, 2008.

My staff completed the on-site part of a reactive inspection on May 28-29, 2008, to evaluate the circumstances of the possible medical event and to assess initial actions prevent a recurrence.

A root or basic cause analysis is pending. The medical center report notes some possible events and causal factors to describe why the patient circumstances occurred.

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

Sincerely,

F. Lynn McGuire
Director, National Health Physics Program

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
3900 Woodland Avenue
Philadelphia PA 19104

MAY 2 8 2008

In Reply Refer To: 642/RSO

Lynn Maguire (VACO)
Director of VA National Health Physics Program
Department of Veterans Affairs
2200 Fort Roots Drive
North Little Rock, AR 72114

Subj: Possible Medical Event at Philadelphia VAMC

1. Please see attached report for the possible medical event that occurred on May 5, 2008 at Philadelphia VAMC.

2. For additional information, please contact our Radiation Safety Officer, Mary E. Moore at (215) 823-5800 X6009.

Richard S. Citron

RICHARD S. CITRON, FACHE
Medical Center Director

Potential Medical Event - NRC Number 44219

Notification of a possible medical event per 10 CFR 35.3045:

A brachytherapy procedure in which the administered dose may differ from the prescribe 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 of Event:	May 5, 2008
Date Discovered:	May 15, 2008
Date Reported to NHPP:	May 15, 2008
Date Reported to NRC:	May 16, 2008
Name of Prescribing Physician:	Richard Whittington, M.D.

Description of the Event:

A permanent implant prostate brachytherapy procedure was performed on May 5, 2008, using I-125 seeds. The activity per seed and number of seeds prescribed in the written directive were ordered and implanted. On May 12, 2008 it was discovered that the activity per seed specified in the Written Directive did not match the activity per seed used in the treatment plan. The treatment plan was re-run on 5-12-08 at 11:13 a.m. with the activity/seed specified on the written directive. The D90 dose was 7% lower than the planned total dose to the prostate, but the difference in D90's between the initial treatment plan and revised treatment plan was more than 30%. As a result of the 30% difference, the RSO determined a Medical Event may have occurred. At 4:00pm on 5-12-08, the referring physician was notified and the patient was called and left a voice mail message requesting he call the Chief of the Radiation Therapy Service. The RSO notified NHPP at approximately 6:15 p.m. Additional evaluation occurred on 5/13/08. Since the terms of the Written Directive were completed as specified, it appeared that no medical event had occurred. A CT scan of the patient was performed on May 6, 2008, and a post-plan was performed on May 15, 2008 to determine if the initial evaluation was correct. The D90 dose, calculated from the post-plan, was less than eighty percent of the prescribed dose. At that point, it was decided to report the occurrence as a possible Medical Event. Post-plans based on CT scans performed approximately one month after an implant, when swelling from the procedure has partially resolved, are believed to provide more accurate assessment of dose to the prostate. The hospital's intention is to have a CT scan and post-plan performed approximately one month after the implant. At that time it will be determined whether a medical event occurred. A causal analysis will be performed and any necessary procedural changes will be implemented to prevent a recurrence before any additional brachytherapy procedures are performed. Also, a formal Root Cause Analysis will be performed

in accordance with the requirements of The Joint Commission (formerly known as The Joint Commission on Accreditation of Health Care Organizations).

Why the Event Occurred:

Root causes of event are believed to be

- Transition to new vendor with corresponding seed model number and seed characteristic changes for treatment planning program.
- Fragmentation of treatment planning process and written directive preparation
- Different activities per seed used by different physicians
- Insufficient double checks following completion of treatment plan and written directive.
- Primary consideration of, and reliance on, Written Directive
- Insufficient double checks before placing order for seeds
- Insufficient double checks by seed vendor

Effect on Patient:

No adverse effect is expected from the lower than intended dose: The patient has been scheduled for a second implant to boost the dose to the originally intended dose. .

Corrective Actions:

Implemented corrective actions include:

- Vendor was notified of the lack of compliance between Written Directive and Treatment Plan. The vendor informed the RSO that their staff was being re-trained to prevent a recurrence.
- Written Directive Form was revised to improve compliance with 10 CFR 35.40
- Pre-completed computerized Written Directive Form was eliminated. A blank Written Directive form is now in the computer and must be completed
- Activity per seed was standardized and will be used by both physicians.
- Checklists for ordering, receipt and seed use in Operating Room were implemented

Corrective actions under review include:

- Determination of best system for double checking prescription and treatment planning phases

Patient notification:

The patient was first called on 5-12-08 and informed on 5-13-08. Subsequent conversations occurred between the Radiation Oncologist and patient. On May 20, 2008 he was informed that he could receive a copy of the written report.