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

AUG 07 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 two 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.

Two medical events were reported to the NRC Operations Center on July 25, 2008. The events 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 related events, assess initial actions to prevent a recurrence, and assess regulatory compliance. This inspection remains open. At the May 29, 2008, exit meeting, the inspectors asked the medical center to review a sample of additional brachytherapy treatments. This review by the medical center is ongoing and has revealed additional patient procedures that meet the definition of a medical event. The NRC Operations Center was notified of these additional medical events on June 6, 12, 21, 25, and July 2, 8, 10, 15, 18, 22, and 25, 2008. The additional events were recorded by the NRC Operations Center as updates to Event Number 44219. This report addresses two of these additional medical events.

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

Sincerely,

E. Lynn McGuire
Director, National Health Physics Program

RECEIVED AUG 11 2008

Enclosure

Potential Medical Event - NRC 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 25, 2008: Two events found

Date Reported to NHPP: July 25, 2008: Two events reported

Date Reported to NRC: July 25, 2008

Name of Prescribing Physician: Gary Kao, M.D., Ph.D.
Richard Whittington, M.D.

Patient XRT #	Implant Date	Original CT Date	# Seeds Recovered	Original Post Plan	Repeat CT	Re-Contour Date	Repeat Rx Plan
061	10-25-04	10-26-04	9	10-27-04	6-26-08	7- 3-08	7-13-08
	2- 7-05	2-8-05	0	2-23-05	6-26-08	7- 3-08	7-13-08
105	8-28-06	8-29-06	0	9-5-06	7-11-08	7-18-08	7-21-08

Description of the Event:

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 CT scans obtained the day after the Implant Date. The first patient listed above had two implants: The total number of seeds recovered for the first implant exceeded 10% but was less than 20%. QA follow-up disclosed the patient was being evaluated for a second implant. The D90 prostate doses for the above 2 patients were significantly lower (more than -20%) than the planned prostate D90 dose.

Implants for both patients are under review to determine the cause of doses being too low by greater than 20%.

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 25, 2008, the RSO and Chief of Radiation Oncology Service completed their review of the results for the above patients and determined Medical Events had occurred. On 7-25-08, 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 and remains on-hold.

Why the Event Occurred:

Currently causal review is still in progress and thus no final determinations as to causality can be concluded. Causal analysis is a charge to the Administrative Board of Investigation (ABOI) that is in process. All external review has been subsumed by and into the ABOI per the PVAMC Director. Final recommendations and completion of the review of the Internal Review Team are pending review of other bodies.
Preliminary observations by the Internal Review Team that require validation and further input include the following:

Lack of proper local Quality Control and Management of brachytherapy program
Lack of policies to address post-implant management of patients and patient dosing
Interruption of connectivity between radiation oncology and radiology for a period of approximately 1 year: This contributed to the inability to calculate patient doses during this time frame, but it was not causative for doses being outside of accepted range

Effect on Patient:

Effects on patients is still being identified and reviewed by both the Internal Review Team and The External Medical Advisory Team

Corrective Actions:

1. The brachytherapy program was placed on hold in early June 2008 pending investigation
2. Institution of local QC/QM program in radiation oncology was established as of July 27 and is ongoing
3. Complete policy review of brachytherapy and development of new policies to address pre and post-implant care; final recommendations are pending the outcome of the ABOI
4. Training of Radiation Oncology staff in radiation safety procedures and in particular to the definition and recognition of a medical event and PVAMC Open Door Policy is in process and is instituted as an ongoing process.
5. Review of procedure to determine the optimal timing of post-implant CT scans (1 day versus 30 day) and to determine the logistics in obtaining such CT scans. Final process policies will be instituted based on the format of brachytherapy in the future as to whether this program will be either "real-time" or whether implants will be performed in the OR as per present protocol.

Patient notification:

On July 25, 2008, the Chief of Radiation Oncology Service phoned one of the above patients and their referring physicians/ primary care providers. Also on 7-25-08, the radiation oncologist for the first patient listed above called that patient and primary care provider. Patients and referring physicians, and/or primary care providers, were informed the patients received a lower than planned prostate dose, that 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.

RT 593 C
FZ 6139
08.11

www.fedex.com/shipping/html/en/PrintIFrame.html

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

FedEx Express

Ship Date: 07AUG08
ActWgt: 0.1 LB
System#: 5250401/INET8061
Account#: S *********

Delivery Address Bar Code

Ref #
Invoice #
PO #
Dept #

SHIP TO: (501) 257-1571 BILL SENDER
Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532

TRK# 0201 7970 4855 6139

FRI - 08AUG A2
STANDARD OVERNIGHT

60532
IL-US
ORD

XH ENLA

FedEx
TRK# 0201 7970 4855 6139

MON - 11 AUG A2
STANDARD OVERNIGHT

60532
IL-US
ORD

XH ENLA

Convention, typic
International Air T

Want more i
Go to **fedex.com**
for international s

100% Recycled Paperboard
MINIMUM 35% POST CONSUMER CONTENT

Emp# 331343 08AUG08 LITA