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

JUL 15 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 seven 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 seven patients was reported to the NRC Operations Center on July 2, 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, and 10, 2008, as amendments to Event Number 44219. This report addresses seven of these additional possible medical events.

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

Sincerely,

for

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

RECEIVED JUL 16 2008

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 1, 2008: Seven events found

Date Reported to NHPP: July 2, 2008: Seven events reported

Date Reported to NRC: July 2, 2008

Name of Prescribing Physician: Gary Kao, M.D. for 6 events
Richard Whittington, M.D. for 1 event

Patient XRT #	M.D.	Implant Date	Original CT Date	Original Pre-Plan	Original Post Plan	Repeat CT	Re-contour Date	Repeat Rx Plan
051	G.K.	3-19-07	3-20-07	3- 6- 07	**6-18-08***	6-19-08	6-20-08	7-1-08
057	GK	12-5-05	12-6-05	11-16-05	6- 1-06	6-19-08	6-20-08	7-1-08
058	G.K.	7-11-05	7-12-05	6-15-05	7-18-05	6-18-08	6-20-08	7-1-08
065	G.K	8-15-05	8-16-05	8- 5-05	9-12-05	6-20-08	6-24-08	7-1-08
066	G.K.	7-18-05	7-19-05	6-20-05	7-26-05	6-19-08	6-20-08	7-1-08
077	R.W.	3-17-08	3-18-08	2-22-08	5-27-08	6-05-08	6-24-08	7-1-08
084	G.K.	8-27-07	8-28-07	5-29-07	Not in Chart	6-19-08	6-20-08	7-1-08

** - CT Data Recovered on 6-6-08*

Description of the Event:

Seven 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. No seeds were recovered in the Operating Room or from the patients during their admissions. The original post-treatment plans were based on a CT scan obtained the day after the Implant Date. The D90 doses for the above patients were significantly lower (more than -20%) than the planned prostate D90 dose.

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 post-treatment plans were run on the respective dates listed above. The updated D90s were still less than 80% of the planned intended prostate dose.

On July 1, 2008, the RSO and Chief of Radiation Oncology Service reviewed these results and determined Medical Events had occurred. On 7-2-08, 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:

Effect on patient is 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 1 and 2, 2008, the Chief of Radiation Oncology Service phoned 6 patients and their referring physicians. Also, one of the Authorized User physicians phoned his one patient on July 2 at 1:45 pm. He also informed this one patient's referring primary care provider on 7-14-08. 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 a written report of the event.

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

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