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

In Reply Refer To: 598/115HP/NLR

OCT 10 2008

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 44524. The report addresses three medical events that occurred at the VA Medical Center, Washington, District of Columbia, and is submitted pursuant to 10 CFR 35.3045(d). The medical center holds VHA Permit Number 08-00942-05 under our master material license.

The three medical events addressed by the enclosed report were reported to the NRC Operations Center on September 26, 2008. The events involved permanent implant prostate seed brachytherapy. These events were discovered as part of an ongoing review implemented in response to events reported earlier for the VA Medical Center, Philadelphia, Pennsylvania.

My staff began a reactive inspection at the permittee's facility on September 30, 2008, to evaluate the circumstances of these events, assess initial actions to prevent a recurrence, and assess regulatory compliance.

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

Sincerely,

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

RECEIVED OCT 14 2008

Department of Veterans Affairs

Memorandum

Date: October 10, 2008

From: Medical Center Director (00/688)

Subj: Possible Medical Event for Three Patients who received Prostate Seed Implantation

To: Director, National Health Physics Program
Thru:

1. The Washington VAMC Radiation Oncology Department provides Palladium Seed implantation for treatment for prostate cancer. In three cases, since November 30th, 2007 the post procedure dose determinations were initially calculated to fall below the 80% D90 threshold. These are possible medical events.

2. Reporting information regarding these events are provided in the attached document.


100908brachy.doc

/s/ Fernando O. Rivera, FACHE

Reporting of a Possible Medical Event:

VA Master Materials License: Permit number: 08-00942-04

Permittee: VA Medical Center, Washington DC

Date(s) of Event(s): See IMPLANT DATES below

Date Discovered: September 28, 2008: Three possible events identified

Date Reported to NHPP: September 28, 2008: Three possible events identified

Date Reported to NRC: September 28, 2008

Name of Prescribing Physicians: William Jackson, MD Jo Ann Manning, MD

Post plan analysis of prostate implants

#	Implant date	CT-date	OR Volume(cc)	Post CT Vol.(cc)	Vol. diff (cc)	CT Vol/OR Vol	Prior D90	Recent CT-Vol	recent D90
1	12/4/2007	12/7/2007	29	43	14	1.48	47	29	80
2	3/5/2008	3/7/2008	30	33	3	1.10	70	31	81
3	4/2/2008	4/4/2008	30	31	1	1.03	52		82

Description of the Event:

These three prostate cancer patients underwent an ultrasound guided prostate implant with Pd^{103} seeds. The prescribed dose was 125Gy. Post implant CT's were performed within 2-3 days of procedure.

For one patient according to the ultrasound images from the OR, the prostate volume was 30cc and 95% of the volume was covered by the prescription dose. The dose to 90% of the volume (D_{90}) was 107% of the prescribed dose. Upon review of the post CT plan the prostate volume was increased to 33cc and the prescribed dose covered 63% of the prostate with a D_{90} of 70%. The patient was asked to return for a late follow-up CT. The prostate volume decreased to 31cc and the D_{90} rose to 80%.

For the second patient, according to ultrasound images during the implant, the prostate volume was 29cc, the prescribed dose covered 95% of the prostate volume and D_{90} was 111% of the prescribed dose. In the post-CT plan the prostate volume increased to 43cc and the percent of the prostate covered by the prescribed dose was 62% and D_{90} was 47%. The patient was asked to return

for a late follow-up CT. The prostate volume decreased from 43 to 29cc and D90 rose to 81%.

The results of these late scans demonstrated a predicted reduction in volume of the prostate gland, bringing the D90 above the 80% threshold in both cases. All of the patients received an adequate dose.

In the case of the third patient, after a review of the prostate volume in the post-CT scan the value of D_{90} is 82%. Thus since November 30, 2007, Washington VAMC has no cases that would be identified as medical events.

Why the Event Occurred:

In review of these events, it is felt that the identified discrepancy occurred due to post implant prostate edema. The timing of the post procedure CT may be the critical element. Early CTs especially when the prostate volume has increased may inaccurately suggest under dosing. A follow up CT, when the prostate volume has returned to OR volumes is important to determine an accurate assessment of dosing.

Effect on Patient:

There were no adverse effects observed in these patients.

Corrective Actions:

Current program processes include the following: The patients' outcomes will continue to be monitored with PSA and H&P. Our current policy is to perform the CT 30 days after the implant to minimize the effect of edema.

The brachytherapy program is currently on hold until further review is completed.

Patient notification:

The two patients in question were notified by the Radiation Oncologist Dr. William Jackson and received a current CT scan October 6, 2008. The results of the late CTs in these patients showed no under dosing.

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

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

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