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

OCT 19 2005

In Reply Refer To: 598/115HP/NLR

Kevin G. Null
Division of Nuclear Material Safety
U. S. Nuclear Regulatory Commission (NRC), Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA

Dear Mr. Null:

I am forwarding the enclosed medical event report for Event Number 42038.

The report is submitted per 10 CFR 35.3045(d) for a possible medical event which occurred on October 3, 2005, at the VA Medical Center, Philadelphia, Pennsylvania, VHA Permit Number 37-00062-07. The possible event was discovered on October 4, 2005, and reported to the NRC Operations Center on October 5, 2005.

My staff completed a site visit October 13, 2005, to evaluate the circumstances of the possible medical event. Ms. Sandra Gabriel, NRC, Region I, accompanied my staff on the site visit. The site visit was closed October 13, 2005. No apparent violations were noted.

The circumstances of this possible medical event were essentially the same as the circumstances of a previous event described in NRC inspection report number 03014526/2003001, of June 30, 2003. For the 2003 event, the NRC concluded the "...occurrence does not constitute a reportable medical event."

Based on the previous NRC conclusion, the current circumstances also do not appear to represent a medical event. If you have any questions, please contact me at (501) 257-1571.

Sincerely,

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
University and Woodland Avenue
Philadelphia PA 19104

In Reply Refer To:

October 18, 2005

VA National Health Physics Program
2200 Fort Roots Drive (115HP)
Building 101, Room 208E
North Little Rock, AR 72114

Dear Mr. Yurko,

Attached is my October 13, 2005 report to the Director of the Philadelphia VA Medical Center Director reformatted as required by Title 10CFR Part35.3045(d). It is being submitted to ensure compliance with NRC required reporting.

Please do not hesitate to contact me at (215) 823-6009, if you would like to discuss this additional information.

Thank you for your assistance with this request.

Sincerely

Mary E. Moore

MARY E. MOORE
Radiation Safety Officer

cc Director

Report of Possible Medical Event

This report is being provided in accordance with the requirements stipulated in Title 10 CFR Part 35.3045(d)

Licensee Name: Department of Veterans Affairs

VHA Permit Number: 37-00062-07

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

Brief Description of Event:

Date of Occurrence: October 3, 2005

Written Directive – 90 Iodine-125 seeds of 0.38mCi/seed activity

Planned Dose to Prostate - 160 Gray (16,000 rad)

Procedure – 90 seeds were inserted into patient as per the Written Directive

Recovered Seeds = 45 total recovered from the bladder in the OR
On 10-4-05, two (2) additional seeds recovered in patient's room

Re-implantation – Recovered seeds were not re-implanted to avoid the possibility of a source being inadvertently cracked during recovering process.

Written Directive Revision – The Authorized User physician revised the Written Directive in the O.R. after the seeds were recovered, but before the procedure was completed. As per normal procedure, the revision to the Written Directive was made to accurately reflect the actual number of implanted seeds remaining in the patient.

Initial Planned Doses:
To Prostate = 160 Gray
Expected Dose to Adjacent Area
Seminal Vesicles = 160 Gray
Rectum = Less than 160 Gray
Bladder = Less than 160 Gray

Calculated Dose to Bladder from Recovered Seeds - Assumes 2 hour residency time
= 14 centiGray/seed in 2hours

Dosimetry for Revised Number of Seeds (45):

Prostate	=	47.14 Gray at D-90
Bladder	=	10 Gray at D43.95
Rectum	=	10 Gray at D31.07
Seminal Vesicle	=	10 Gray at D89.78

Notifications:

RSO - RSO Staff immediately informed the RSO upon their return from the Operating Room on 10/3/05. RSO reviewed events with Radiation Safety staff, Radiation Oncology Physicist, and Authorized User. Greater than 20% difference occurred between actual and initial planned number of seeds. Authorized User revised Written Directive to accurately account for actual number of seeds implanted and recovered before completion of the procedure. Regulations were reviewed. The Director and Associate Director were informed of the possibility of a medical event. The NHPP Regional Manager was also notified that evening.

Patient and Referring Physician – Due to the patient's medical condition, the Authorized User informed the patient's daughter on 10/5/05 about the number of seeds implanted. The referring physician was the Attending Urologist who assisted with the implant. He was aware of the reduced number of seeds.

Post-Implant Evaluation

Post-treatment CT was scheduled for early 10/4/05 to facilitate dosimetry evaluation and determination if a medical event occurred. All options affecting dose were reviewed on October 4 and 5 with the Authorized User, the Chair of Radiation Oncology and Radiation Therapy Physicists. The dose reduction to the prostate was more than 20% lower than expected from the 50% reduction in the number of seeds implanted.

Evaluation by RSO:

This event may meet the regulatory criteria of a Medical Event.

Why the Event Occurred:

The actual cause has not been determined at this time and is under review. A Root Cause Analysis will be performed to review this case in depth. It is suspected the lack of pre-surgical GI preparation, as wells as interrupting the implant to address GI issues, and re-initiating the ultrasound probe placement and patient positioning were key factors.

The Effect, if any, on the Individual Who Received the Administration:

The effect on the tumor cannot be determined at this time. No deleterious effect to surrounding tissue is expected

What Actions, if any, Have Been Taken, or Are Planned to Prevent Recurrence:

On October 3, 4 and 5th, this case was reviewed by the Radiation Oncologist who performed the procedure, the Chief of Radiation Oncology, the Radiation Oncology Medical Physicist and the Radiation Safety Officer. Administration directed that a Root Cause Analysis Team be assembled to do an in-depth review to determine cause and recommend corrective actions to prevent a recurrence. On October 12, 2005 the ultrasound equipment vendor (B-K) evaluated the ultrasound equipment to determine if it was working properly. Ultrasound equipment QC will also be addressed during the RCA. The results of these reviews will be analyzed to identify cause and facilitate effective corrective action.

MARY E. MOORE
Radiation Safety Officer

cc Director
Associate Director
Radiation Safety Committee
File

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