



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

FEB 10 2009

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 44813. The report addresses two medical events that occurred at the VA Greater Los Angeles Healthcare System, Los Angeles, California, and is submitted pursuant to 10 CFR 35.3045(d). The healthcare system holds VHA Permit Number 04-00181-04 under our master material license.

The two medical events involve permanent implant prostate brachytherapy using iodine-125 seeds. The events were discovered by healthcare system staff on January 27, 2009, and reported to the NRC Operations Center on January 28, 2009. The events were discovered by a review requested during a National Health Physics Program inspection on January 21-22, 2009, which remains open.

These two events are interpreted to meet the definition of a medical event under 10 CFR 35.3045(a)(3), dose to tissue other than the treatment site greater than 50 rem and 50% of the expected dose; this is a correction to our earlier report to the NRC Operations Center on January 28, 2009, in which we inadvertently characterized the events as medical events under 10 CFR 35.3045(a)(1)(i), dose to the treatment site more than 20% below the prescribed dose.

For your information, the enclosure references "R100" as a dose parameter. R100 is the volume of the rectum receiving at least 100% of the dose prescribed to the prostate. An R100 less than about 1 cc is associated with a low incidence of deterministic biological effects on the rectum.

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

Sincerely,

A handwritten signature in black ink, appearing to read "E. Lynn McGuire".

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

RECEIVED FEB 11 2009

**DEPARTMENT OF
VETERANS AFFAIRS****Memorandum**

Date: February 5, 2009

From: Director, VA Greater Los Angeles Healthcare System (691/00)

Subj: 15-day Report for Two Medical Events

To: Director, VHA National Health Physics Program (115HP/NLR)
THRU: Chief of Staff, VA Greater Los Angeles Healthcare System (691/11)

1. The VA Greater Los Angeles Healthcare System reported two medical events in the prostate brachytherapy program to Dr. Ed Leidholdt on January 27, 2009. The telephone report was made to meet the requirements of 10 CFR 35.3045.
2. The written report that is required to be submitted to the appropriate Nuclear Regulatory Commission Regional Office within 15 days is enclosed. The report includes the items required by 10 CFR 35.3045 (d).



Donna M. Beiter, RN, MSN

Attachment

REPORT OF MEDICAL EVENTS

Permittee: VA Greater Los Angeles Healthcare System (GLA) (Permit Number 04-00181-04)

Prescribing Physician: John W. Horns, MD

Description of Events: In response to the recent medical events at other Department of Veterans Affairs (VA) facilities, GLA reviewed several previous prostate brachytherapy cases at the request of the VA's National Health Physics Program during an on-site inspection January 21-22, 2009. Two cases appear to have met the definition of a medical event.

Case 1: On June 8, 2005, a patient was implanted, for prostate cancer, with 62 iodine-125 seeds with a total activity of approximately 20.3 mCi. The dose prescribed in the pre-implantation portion of the written directive was 145 Gy to the prostate. A post-implant dose assessment was performed on February 2, 2006, where the D90 was 71.8 percent and the D80 was 84.7 percent. At that time, an assessment of seeds outside the prostate was not performed. In addition, at that time, GLA considered a medical event to have occurred if D80 was 80 percent or less.

On January 27, 2009, GLA completed a review of the case which included performing another post-implant evaluation and dose assessment. The results indicated that the D90 was 67.1 percent and the D80 was 83 percent. In addition, it was determined that 8 seeds were more than one centimeter outside the prostate and two seeds were more than 1.5 centimeters outside the prostate. The seeds were concentrated in non-critical tissue. The R100 was determined to be 0.36 cc. As a result, it was determined that there were likely enough seeds outside the prostate to have resulted in a dose to a tissue in excess of 50 rem and more than 50 percent of what was expected by the treatment plan. In addition, the resultant dose to the prostate differed from the prescribed dose by more than 20 percent.

Case 2: On November 23, 2005, a patient was implanted, for prostate cancer, with 88 iodine-125 seeds with a total activity of approximately 28.8 mCi. The dose prescribed in the pre-implantation portion of the written directive was 80 percent of the prostate volume to receive at least a total dose of 145 Gy. A post-implant dose assessment was performed on March 1, 2006. At that time, an assessment of seeds outside the prostate was not performed.

On January 27, 2009, GLA completed a review of the case which included performing another post-implant evaluation and dose assessment. It was determined that 13 seeds were more than one centimeter outside the prostate and one seed was more than 1.5 centimeters outside the prostate. The seeds were concentrated in non-critical tissue. The R100 was determined to be 0.77 cc. As a result, it was determined that there were likely enough seeds outside the prostate to have resulted in a dose to a tissue in excess of 50 rem and more than 50 percent of what was expected by the treatment plan.

Why the Events Occurred: A causal analysis is in progress and will include the identification of root causes. At this time, the preliminary causes for the seeds being outside the prostate are attributed to the poor quality of the ultrasound unit that was used during the procedure and the lack of a structured resident training program in prostate

brachytherapy. The GLA program in 2005 was structured such that inexperienced residents were allowed to implant needles (seeds) under the direction of the attending. In addition, in 2005, the ultrasound unit that was available for use for guiding the needles was limited in its capability to provide high quality images. An additional preliminary cause for the second case is that prompt post-plans were not being developed. Had the post-plan for the first case been more timely and included an evaluation of seeds outside the prostate, actions may have been taken sooner to ensure more accurate seed placement in future cases.

These events were not reported as medical events at the time because non-critical tissues were not considered in the pre-plan, and as a result, were not evaluated as part of the post-plan. Additionally, GLA interpreted the criteria of a medical event to be when D80 was 80 percent or less. The written directive for Case 1 did not explicitly prescribe to the D80, but it was explicit in the written directive for Case 2.

Effect on the patients: Based on the location of the seeds outside the prostate, no adverse deterministic effects are expected. Furthermore, a review of both patients' medical charts did not reveal any adverse deterministic effects to the tissues that were exposed. The lower than expected doses to the prostate may increase the chance of disease recurrence. The patients will continue to be monitored and evaluated for appropriate follow-up medical care.

Corrective Actions: The immediate corrective actions address the preliminary causes previously discussed in this report. A new trans-rectal ultrasound unit capable of providing high quality images has been used since January 2007. Implantation by resident physicians has not occurred since the June 20, 2007, implants, but will occur in the future under more strict guidelines after sufficient training. A new attending physician is being trained at GLA by an experienced proctor. The proctor will continue to participate in the procedures until the new physician is able to demonstrate that she can perform the implants independently and with results that meet current clinical standards. She has completed two implants with the proctor that met current clinical standards. The future training of any residents will not occur until the new physician is fully trained and an appropriate training program is developed.

Corrective actions to more timely identify potential medical events in the future will include reviewing of the 3-D seed distribution images created in the treatment planning program. More timely post-plan evaluations were implemented in late 2005. In addition, clear criteria will be established that relate practical parameters to the definitions of a medical event. Finally, the key personnel involved in the program have been re-trained on what constitutes a medical event based on recent guidance from the VA's National Health Physics Program.

A causal analysis will be completed and any additional corrective actions will be addressed.

Patient Notification: One patient was notified of the event on January 28, 2009. An attempt was made to notify the other patient on January 28, 2009, but it was unsuccessful. This patient was ultimately notified of the event on January 29, 2009.

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



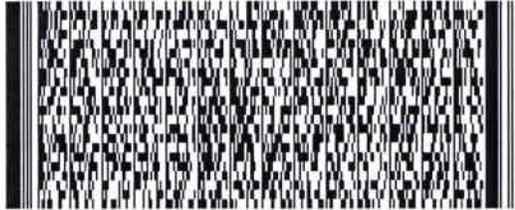
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SHIP TO: (501) 257-1571 **BILL SENDER**
Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532

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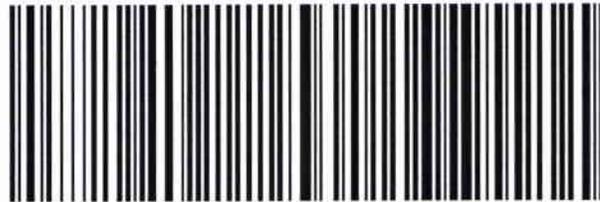


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