



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

**FEB 24 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 44853. The report addresses one medical event 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 medical event involved permanent implant prostate brachytherapy using iodine-125 seeds. The event was discovered by healthcare system staff on February 12, 2009, and reported to the NRC Operations Center on February 13, 2009. This event is being reviewed as part of an ongoing NHPP inspection of this permittee.

For your information, the enclosure refers to "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 below 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 26 2009

**DEPARTMENT OF  
VETERANS AFFAIRS**

**Memorandum**

Date: February 19, 2009

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

Subj: 15-day Report for a Medical Event

To: Director, VHA National Health Physics Program (115HP/NLR)  
THRU: Chief of Staff, VA Greater Los Angeles Healthcare System (691/00) *CLG*

1. The VA Greater Los Angeles Healthcare System reported a medical event in the prostate brachytherapy program to Dr. Ed Leidholdt and Gary Williams on February 13, 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 EVENT

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

**Prescribing Physician:** John W. Horns, MD

**Description of Event:** On February 12, 2009, a patient was implanted, for prostate cancer, with 108 iodine-125 seeds with a total activity of approximately 39.0 mCi. The dose prescribed in the pre-implantation portion of the written directive was 145 Gy to the prostate. A post-implant image was taken in the operating room following the procedure to evaluate seed placement. The image revealed that several seeds were outside the prostate. A post-implant CT and pelvic x-ray were performed later the same day where it was determined that five seeds within the same strand (1.8 mCi total) were more than one centimeter outside the prostate and in non-critical tissue. 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 Event Occurred:** The event occurred because seeds were incorrectly positioned. The exact cause of the incorrectly positioned seeds is not yet known. A suspected cause is that during the placement of one strand the needle was not fully retracted to the hub of the stylet. As a result, the seed strand could have hung in the needle and was subsequently dislodged at another location when the needle was being removed. A causal analysis is in progress.

**Effect on the patient:** The final D90 of the prostate is not yet known, but based on the initial measurements of the post-operative edematous prostate the D90 was 88.4 percent and the R100 was 0.20 cc. Based on the location of the seeds outside the prostate, no adverse deterministic effects are expected. The patient will continue to be monitored and evaluated for appropriate follow-up medical care.

**Corrective Actions:** The prostate implant program at GLA was suspended by the GLA Chief of Staff on February 13, 2009. The program will not restart until a causal analysis of this event is completed. Any root causes identified will be addressed before the program resumes.

**Patient Notification:** The patient was notified of the event on February 13, 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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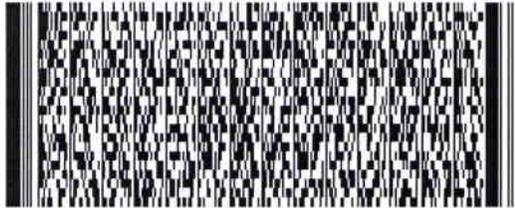
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SHIP TO: (501) 257-1571 **BILL SENDER**  
**Cassandra Frazier**  
**Nuclear Regulatory Commission**  
**2443 Warrenville Road**  
**Suite 210**  
**Lisle, IL 60532**

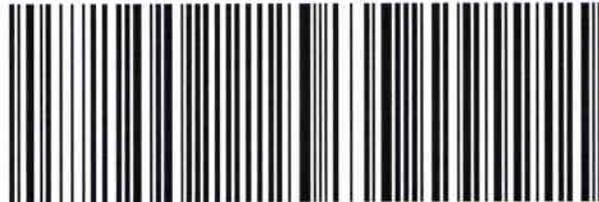


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