



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

DEC 01 2008

In Reply Refer To: 598/115HP/NLR

Cassandra Frazier
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 Ms. Frazier:

I am forwarding the enclosed medical event report for Event Number 44663. The report addresses one medical event that occurred at the VA New York Harbor Healthcare System, Brooklyn, New York, and is submitted pursuant to 10 CFR 35.3045(d). The healthcare system holds VHA Permit Number 31-02892-03 under our master material license.

The medical event addressed by the enclosed report was reported to the NRC Operations Center on November 18, 2008. The event involved permanent implant prostate seed brachytherapy. The event was discovered as part of an ongoing review implemented in response to events reported earlier for the VA Medical Center, Philadelphia, Pennsylvania.

My staff initiated an on-site reactive inspection on November 20, 2008, to evaluate the circumstances of the medical event, initial actions to prevent a recurrence, and assess regulatory compliance. The inspection remains open pending further review.

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

Sincerely,

Handwritten signature of E. Lynn McGuire in black ink.

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

Written Report of Medical Event
Part 35.3045(d)

David Schwartz, M.D.
Chief, Radiation Oncology
Date: 11/22/2008

1. Licensee's name: New York Harbor Health Care System / Brooklyn Campus. Permit # 31-02892-03

2. Prescribing physician's name: David Schwartz M.D. (authorized user)
Referring Physician: William Blank M.D, Chief Urology

3. A brief description of the event: A Prostate Brachytherapy post-plan was performed approximately 4 weeks after delivery of prostate brachytherapy, it was appreciated that the D90 was 69%. Dr. Schwartz discussed this under dosage in the anterior aspect of the prostate with the patient and with urology and indicated to them that a supplemental implant was needed. Dr. Schwartz performed touch up implant successfully, with a final D90 of 90%. Date of first implant: 9/18/08, post CT: 10/10/08 and touch up was performed on October 30, 2008.

4. Why the event occurred: The event occurred because 3 seeds were placed lower than the prostate region.

5- The effects, if any on the patient: There is no harm to the individual patient; the final D90 was quite adequate. Additionally, rectum, bladder and urethra were not overdosed by the seeds that were placed lower than intended.

6- Future actions for preventing recurrence: Extreme care is always taken in delivery of needles/seeds. An unusual event occurred and care will be taken to assure it does not recur.

7. Notification to the patient: Both the department of Urology and the patient were made aware that a touch up implant was needed. The notification was included in the patient's chart, and informed consent was obtained. In addition Dr. Schwartz informed the patient that the touch up implantation was successfully performed.

8: A copy of this report with the patient's name will be kept in the patient's chart and will be sent to the hospital performance improvement manager and the referring physician. In addition the event will be discussed in the radiation safety committee.

9. Addition comments by Dr. Schwartz:

Written NRC Requirements for reporting under dosage in regards to D90 coverage of prostate brachytherapy implants are vague. If necessary I always intend to supplement prostate brachytherapy implants with a touch up implant, based on a low D90 (<80%)

coverage or based on what I perceive as inadequate coverage. I had perceived inadequate D90 coverage as reportable if 90 percent of the prostate was not covered by the 80% isodose line after a touch up implant (if needed), or if a touch up implant was not feasible. This makes sense, as the half life of I-125 is 60 days. Doing a touch up implant within the first several weeks of the first implant, if needed, is good clinical practice.

When our team learned that NRC looks at the definition of D90 coverage as D90 coverage with seeds delivered prior to a patient leaving the operating room, the NRC was informed of the event. Thus, the NRC was informed of this event within 24 hours of realization a medical event had occurred.

David Schwartz M.D.
Chief, Department of Radiation Oncology

Esfandiar Sarfaraz, Ph.D.
Radiation Safety Officer