



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

MAR 26 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:

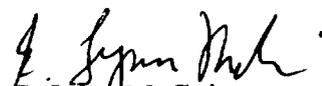
I am forwarding the enclosed medical event report for Event Number 44065. The report is in the format of a letter signed by the permittee director and has the information required per 10 CFR 35.3045.

The report is submitted per 10 CFR 35.3045(a)(2) for a possible medical event which occurred on March 14, 2008, at the VA Medical Center, San Francisco, California, VHA Permit Number 04-00421-05. The possible event was discovered on March 14, 2008, and reported the same day to the NRC Operations Center.

My staff initiated an on-site reactive inspection on March 18, 2008, to evaluate the circumstances of the possible medical event and to assess initial actions to prevent a recurrence. The inspection and conclusion about whether the patient circumstances meet the dose threshold for a medical event in 10 CFR 35.3045(a)(2) remain open pending further review.

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

Sincerely,


E. Lynn McGuire
Director, National Health Physics Program

Enclosure

RECEIVED MAR 28 2008



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
4150 Clement Street
San Francisco, CA 94121

In Reply Refer To:

March 25, 2008

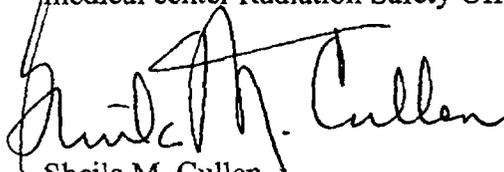
Permit No. 04-00421-05

Director, VHA National Health Physics Program (115HP/NLR)
2200 Fort Roots Drive
Building 101
North Little Rock, Arkansas 72114

Subj: 15-Day Written Report for a Potential Medical Event

Attached is a 15-day written report for a potential medical event. While the medical center is still in the process of investigating this potential medical event, be assured that all steps and resources are mobilized to continue to provide the highest quality patient care and to maintain the highest radiological standards. The prostate brachytherapy program has been in place for ten years, during which care to veterans has been second to none in the area of patient care and radiological support. It is my intent to address/resolve this issue and continue providing the care most greatly deserved by our veterans.

If you have any further questions, or if we can provide any further assistance, please contact the medical center Radiation Safety Officer, Mr. Arnulfo A. Germes, at 415-720-9732.


Sheila M. Cullen
Medical Center Director

15-Day Written Report for Event Number 44065

1. The licensee's name:

a. Licensee:

Department of Veterans Affairs
Under Secretary for Health
NRC License No. 03-23853-01VA

b. Permittee:

VA Medical Center, San Francisco, California
VHA Permit No. 04-00421-05

2. The name of the prescribing physician: Patrick S. Swift, M.D.

3. A brief description of the event:

The medical center scheduled three patients for permanent implant seed brachytherapy on March 14, 2008. The medical center had received three packages of iodine-125 seeds in preloaded sterile needles earlier in the week. The packages did not show any evidence of damage or removable contamination when received.

The authorized user began the procedure and implanted 12 seeds of the prescribed 106 seeds into the first patient. Concurrently, the radiation safety staff identified apparently fixed contamination on sterile plastic wrap and a clear plastic tray that had contained the preloaded seeds and needles. When informed of the contamination, the authorized user stopped the procedure. The authorized user documented, on the written directive, the implantation that had been performed. The patient was given non-radioactive iodine to block his thyroid.

The radiation safety staff wiped and surveyed the inner sterile plastic wrap and the plastic trays for the second and third patients and did not identify any contamination.

The second patient procedure was then completed. Surveys after the procedure indicated the tips of two needles used in the procedure had readings above background but not the other 22 needles.

The third patient procedure was cancelled.

Urine bioassays of the first and second patients show evidence of Iodine-125 excretion. The total excretion by the first and second patient by March 25, 2008, is estimated to be approximately 155 and 0.1 microcuries, respectively. A thyroid bioassay on March 24, 2008 of the first patient indicated a thyroid uptake of approximately 0.54 microcuries.

Both patients are being administered stable iodine to protect their thyroids and are being followed clinically to assess their internal radioiodine levels.

15-Day Written Report for Event Number 44065

The vendor of the seeds was notified of the event on the day of the procedures. Plans are being made to return to the vendor for examination the unused needles containing seeds and the contaminated empty used needles.

4. Why the event occurred:

The causes of this possible medical event are under investigation and not yet determined. It is unlikely that any actions by medical center staff caused seed leakage.

5. The effect, if any, on the individuals who received the administration:

Both patients have been seen by a Medical Center endocrinologist and have received appropriate thyroid protection. Their primary physicians have also been informed. The plan is to give ongoing clinical follow-up to these patients. The clinical opinion is that no adverse effects to the patients are expected.

6. What actions, if any, have been taken or are planned to prevent recurrence:

Routine patients who had been scheduled for seed brachytherapy in the next two weeks have been temporarily postponed. The single patient whose implantation was only partially performed may have it completed during this period.

A review of this possible medical event and the seed brachytherapy program is in progress.

The Radiation Safety Committee will evaluate findings and lessons learned determined during the review and implement corrective actions to prevent recurrence.

7. Certification that the licensee notified the individuals:

Clinical disclosure was done and documented for both patients.

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Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 605324352



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