UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 30, 2003

Docket No. 03014526 License No. 37-00062-07

Michael J. Sullivan
Director
Department of Veterans Affairs Medical Center
University & Woodland Avenue
Philadelphia, PA 19104

SUBJECT: INSPECTION 03014526/2003001, DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER, PHILADELPHIA, PENNSYLVANIA SITE

Dear Mr. Sullivan:

On February 19, 2003, Penny Lanzisera of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of an event that occurred on February 3, 2003 that you reported to the NRC on February 14, 2003. Additional information provided in the telephone conversation on March 13, 2003 between Ms. Mary Moore of your organization and this office was also examined as part of the inspection. The findings of the inspection were discussed with you and members of your staff at the conclusion of the inspection. The enclosed report presents the results of this inspection.

Within the scope of this inspection, no violations were identified.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm.html. No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03014526/2003001

cc:
Mary E. Moore, Radiation Safety Officer
Commonwealth of Pennsylvania

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03014526/2003001
Docket No.	03014526
License No.	37-00062-07
NMED Report No.	39586
Licensee:	Department of Veterans Affairs Medical Center
Location:	University and Woodland Avenue Philadelphia, Pennsylvania 19104
Inspection Dates:	February 19, 2003
Date Followup Information Received:	February 21 and 27, 2003

Inspector:

Penny Lanzisera — date
Senior Health Physicist

Approved By:

Original signed by
Pamela J. Henderson — ***June 30, 2003***

Pamela J. Henderson, Chief — date
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Document Name: C:\ORPCheckout\FileNET\ML031820592.wpd

EXECUTIVE SUMMARY

Department of Veterans Affairs Medical Center
NRC Inspection Report No. 03014526/2003001

An announced special inspection was performed on February 19, 2003, to review the circumstances surrounding a possible medical event that was reported to the NRC by the licensee on February 14, 2003 and that occurred on February 3, 2003. The event involved a prostate implant where 74 iodine-125 seeds of 0.38 millicurie/seed were implanted in a patient's prostate and 40 seeds were recovered from the bladder. The authorized user determined that it was unsafe to re-implant the recovered seeds and revised the written directive to accurately reflect the actual number of seeds remaining in the patient. The revision to the written directive was documented prior to completion of the operating room portion of the procedure. The licensee's review of the root cause is still on-going, however, the data suggests that the ultrasound reference points were either misleading or misinterpreted resulting in placement of several needles directly into the bladder.

The licensee submitted a written report dated February 27, 2003, as required by 10 CFR 35.3045, in the event that the NRC determined that the event constituted a medical event. In the report, the licensee described actions taken or planned to prevent recurrence. On June 13, 2003, the NRC concluded that "this occurrence does not constitute a reportable medical event."

Within the scope of this inspection, no violations were identified.

REPORT DETAILS

I. Event Description

a. Inspection Scope

The inspection focused on a review of the prostate implant program and the circumstances surrounding the possible medical event that was reported to the NRC in accordance with 10 CFR 35.3045. The inspection of the event consisted of observations by the inspector, interviews with involved personnel, and a selected examination of records describing the event and followup actions. A chronology of the event is described below.

b. Observations and Findings

Prostate Implant Program

The licensee recently started the prostate implant program and had performed 9 cases prior to this event. Iodine-125 as presterilized seeds in preloaded needles is used for implants.

Incident Chronology

February 3 Prior to the implant, the written directive was reviewed and signed by the authorized user. The written directive noted that 74 seeds, with a total activity of 28.12 millicuries, were to be implanted into the patient's prostate to deliver a dose of 160 Gray to the treatment site. The urologist, a senior resident, determined the correct positioning with an ultrasound probe and the attending urologist verified the positioning. The authorized user was called to the operating room and also verified the positioning with the resident urologist. The authorized user implanted the 74 seeds. Several factors were encountered during the treatment, including, insertion of seeds into a small prostate, suboptimal positioning of the ultrasound probe and the patient, and rectal gas resulting in placement of a rectal tube during the procedure. Upon completion of the implant, the resident urologist performed a cystoscopy on the patient and noted that several sources were located in the bladder. The urologist removed 40 seeds from the bladder. Since the retrieved seeds were contaminated with blood and urine, the authorized user decided not to re-implant the 40 seeds. The authorized user noted this revision on the written directive and indicated that only 34 seeds were implanted in the prostate. The patient and the patient's spouse were notified that the procedure was incomplete and that a followup treatment may be necessary.

February 4 Radiation Safety Committee Chair briefed on event and determined that event did not constitute a reportable medical event.

February 6 Event reported to the Veterans Administration's Center for Patient Safety.

February 12 Event discussed at Radiation Safety Committee meeting. The Committee decided to report the event to the Veterans Administration's National Health Physics Program.

February 13 National Health Physics Program reviewed event and determined that the event may be a reportable medical event.

February 14 NRC notified of possible medical event.

February 27 Written report submitted in accordance with 10 CFR 35.3045. The licensee concluded that the event did not meet the regulatory criteria of a "medical event." In addition, the licensee stated that "no deleterious effect is expected from splitting the initial treatment from one into two fractions" and the unintended dose to the bladder "is not expected to cause any injury."

March 3 Patient re-scheduled for remainder of treatment. However, treatment was postponed.

Notification of the Event

On February 14, 2003, the licensee notified the NRC Operations Center of the possible medical event involving an iodine-125 prostate implant, as required by 10 CFR 35.3045. During the inspection on February 19, 2003, the attending urologist stated that the patient was notified of the event on February 3, 2003. Additionally, the authorized user discussed the event with the patient during a telephone conversation on February 6, 2003. A written report of the event was submitted to the NRC on February 27, 2003, in case the event was classified as a reportable medical event. The report indicated that the initial planned dose was 160 Gray to the prostate with an expected dose of 25 Gray to an area of 4 cubic centimeters of the bladder. The actual dose to the prostate from the implant was 75 Gray to 10% of the prostate, 20 Gray to 5% of the bladder, and less than 5 Gray to 95% of the bladder. On June 13, 2003, the NRC determined that "this occurrence does not constitute a reportable medical event."

No violations of 10 CFR 35.3045 requirements were identified.

Licensee's Corrective and Preventive Actions

During the inspection conducted on February 19, 2003, and in their report dated February 27, 2003, the licensee provided the following corrective and preventive actions:

1. Peer reviews were requested and a root cause analysis was initiated. The results of these reviews will be analyzed by the licensee to identify cause and implement corrective actions.

2. On February 28, 2003, the ultrasound equipment manufacturer evaluated the unit used during the treatment and found the unit operational.

3. Whenever possible, the attending urologist will be present at the beginning of all treatments to verify positioning.

c. Conclusions

The licensee implanted 40 iodine-125 seeds into the bladder instead of the prostate, the intended treatment site. As a result, the bladder received an unintended dose and the prostate received an underdose. The licensee immediately identified this error and removed the seeds from the bladder. Since the authorized user revised the written directive prior to completion of the procedure in the operating room to document the actual number of seeds implanted in the prostate and since the unintended dose to the bladder did not exceed 50% of the expected dose to this area from the procedure, this event does not constitute a medical event. In addition, the licensee's implemented and planned corrective actions appear comprehensive.

No violations of 10 CFR Part 35 or 10 CFR Part 20 requirements were identified.

II. Written Directive Procedures

a. Inspection Scope

The licensee's procedures for administrations requiring a written directive were reviewed during the inspection. In particular, the implementation of the procedures and adequacy for the prostate implant program were reviewed. The inspection of the procedures developed in accordance with 10 CFR 35.41 consisted of a selected examination of records documenting the program and its implementation in this case, and interviews of licensee personnel.

b. Observations and Findings

10 CFR 35.41 requires, in part, that the licensee develop, implement, and maintain written procedures to provide high confidence that licensed material or radiation from licensed material will be administered as directed by the authorized user.

To meet the objectives of 10 CFR 35.41, the licensee's procedures require: i) an authorized user will sign and date a written directive prior to implantation of brachytherapy sources; ii) prior to implantation, the patient will be identified; iii) a treatment plan will be developed which shall contain the number of sources, the source strength, and if applicable, the loading sequence; iv) an authorized user or the medical physicist will review the treatment plan to assure the final plans of treatment and related calculations are in accordance with the written directive; and v) the individual who administers the dose shall date and sign a record of the treatment after the brachytherapy procedure is completed.

The inspector confirmed that an appropriate written directive was prepared and signed and the patient was verified prior to implantation. The inspector also confirmed that the authorized user verified the plan of treatment with the medical physicist prior to the implantation. A written record of the actual treatment given was also appropriately prepared, signed, and dated by the authorized user who was involved in the implant.

c. Conclusions

The licensee's implementation of their written directive procedures specific to prostate implants is adequate and meets the requirements in 10 CFR 35.41. No violations of 10 CFR 35.41 requirements were identified.

III. Exit Meeting

An exit meeting was conducted with the staff identified in the next section at the conclusion of the inspection on February 19, 2003.

PARTIAL LIST OF PERSONS CONTACTED

Licensee
*Michael J. Sullivan, Medical Center Director
*William S. Scott, Vice President for Clinical Support Services
*Mary Moore, Radiation Safety Officer
Meg O'Shea Caplan, Chief Operating Officer
E. Marteena Session, Radiation Safety Staff
Richard Shimko, Radiation Safety Staff
Martin F. Heyworth, M.D., Chief of Staff
S. Bruce Malkowicz, M.D., Attending Urologist and Chief of Urology
Christopher Woodard, M.D., Chief Resident, Urology
Gary Kao, M.D., Radiation Oncologist
Gregory Desobry, Ph.D., Medical Physicist
Linda Aumiller, Patient Safety Risk Manager
Mary Scanlon, M.D., Radiation Safety Committee Chair
*Paul Yurko, Health Physicist, National Health Physics Program

*indicates presence at exit meeting