

Region I
NMSS Licensee Event Report

License No. 37-0018-07

Docket No. 030-02939

MLER-RI 2001-023

LICENSEE: UNIVERSITY OF PENNSYLVANIA.

EVENT DESCRIPTION MISADMINISTRATION

EVENT DATE 5/4/2001 REPORT DATE 5/16/01

1. **REPORTING REQUIREMENT**
- 10 CFR 20.2201 Theft or Loss
 - 10 CFR 20.2203 30 Day Report
 - 10 CFR 30.50 Report
 - Other 10 CFR 35.33
- 10 CFR 35.33 Misadministration
 License Condition

2. **REGION I RESPONSE**
- Immediate Site Inspection
 - Special Inspection
 - Telephone Inquiry
 - Preliminary Notification
 - Information Entered on the RI Log
 - Review at Next Routine Inspection
 - Report Referred to _____
- Inspector/Date 5-7-01
Inspector/Date _____
Inspector/Date _____
 Daily Report

3. **REPORT EVALUATION**
- Description of Event
 - Levels of RAM Involved
 - Cause of Event
 - Corrective Actions
 - Calculation Adequate
 - Letter to Licensee Requesting Additional Information

4. **SPECIAL INSTRUCTIONS OR COMMENTS**

Completed By: Penny Hansen Date 5-29-01

Reviewed By: [Signature] Date 5/31/01

UNIVERSITY of PENNSYLVANIA

RECEIVED
REGION 1

Environmental Health & Radiation Safety

3160 Chestnut Street
Suite 400
Philadelphia, PA 19104-6287
Tel. (215) 898-4453
Fax: (215) 898-0140

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May 16, 2001

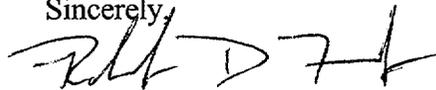
Penny Lanzisera
Nuclear Materials Safety Branch
United States Nuclear regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Ms. Lanzisera:

As required by 10 CFR 35.33, I enclose a report of the May 4, 2001 misadministration at the University of Pennsylvania (NRC License # 37-00118-07).

If you need further information, please contact me at (215) 898-2109.

Sincerely,



Robert D. Forrest, CHP
Associate Director/Radiation Safety Officer

cc: Richard Whittington, MD
Cameron Koch, Ph.D.

01-00645 RF-dpr

Licensee: University of Pennsylvania (NRC License #37-00118-07)

Prescribing Physician: Dr. Richard Whittington

Description of Event:

At approximately 10:00 am on May 4, 2001, Dr. Whittington, an authorized user in Radiation Oncology, administered a prostate implant involving 94 seeds containing a total of about 48 mCi of I-125, in accordance with the written directive for the treatment.

After the completion of the procedure, radiation surveys detected radiation levels greater than background from one of the applicator needles. After not visibly noting a seed, removable contamination of about 50 nCi was identified on the applicator needle indicating a possible leaking source. Assays of the patient's urine were positive for I-125, confirming that a source had leaked. Additional radiation surveys indicated no contamination on any object or area associated with the treatment or with the source use, storage, or shipment.

The patient was administered Lugol's solution (potassium iodide) to minimize the unintended I-125 thyroid uptake from the leaking seed. Thyroid bioassays were performed on May 5, May 8 and May 16, 2001. Based on these measurements, a dose to the thyroid of approximately 4.1 rads was calculated.

Why the event occurred:

Immediately after the implant, four seeds were found in the bladder. They were retrieved from the bladder with biopsy forceps, loaded into another applicator needle, and re-implanted into the prostate. The biopsy forceps most likely damaged one of the seeds.

Effect on the individual:

The effect on the individual who received the misadministration was an unintended thyroid dose of approximately 4.1 rads. No clinically observable effects are expected as a result of this thyroid dose.

Improvements and actions to prevent reoccurrence:

The prostate brachytherapy protocol has been modified to incorporate additional survey requirements during implant procedures. When seeds are retrieved from the bladder, they will be placed on a small gauze pad. After removing the seed from the gauze pad, the gauze pad and biopsy forceps will be surveyed in a low background area. If contamination is detected, the seed will not be re-implanted.

Notification:

Dr. Whittington informed the patient on May 4, 2001. The individual was notified that one of the implanted seeds was leaking and that some or all of the radioactive iodine from this seed would enter his systemic circulation and accumulate in his thyroid. For this reason, the patient was told that he was being administered Lugol's solution, a non-radioactive iodine solution, to minimize the thyroid uptake of the radioactive iodine. Dr. Whittington informed the patient that his urine would be also be radioactive. To minimize the spread of contamination, he should sit down to urinate for several days and wash his hands thoroughly after each voiding. These instructions were re-emphasized by health physicists from the radiation safety staff on May 4 and May 5, 2001.