1/23/97 RIDS EVENTS DIST
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EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT NO. KY - 96 - 02

DATE: JANUARY 13, ~~1997~~

PM2 1/23/97

TO:

~~Deputy Director~~
Office of State Programs

SUBJECT: MISADMINISTRATION THAT OCCURRED ON OCT. 16, 1996, at the UNIVERSITY of LOUISVILLE, LOUISVILLE, KY, INVOLVING CS-137 BRACHYTHERAPHY SOURCE

(PROPOSED AO)

STATE: KY

Signature and Title: Vicki L. Jeffs, Supervisor

Radioactive Materials Program

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SP-E-9

NRC FORM 566 (4-94) U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0178
EXPIRES: 04/30/97

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 1 HOUR. THIS INFORMATION IS REQUESTED TO ASSESS MISADMINISTRATIONS AND EVALUATE ACTIONS NECESSARY TO PREVENT THEIR RECURRENCE. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0178), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

MEDICAL MISADMINISTRATION

LICENSEE	CITY AND STATE	ORIGINAL ITEM NUMBER
University OF Louisville	Louisville, KY	
TYPE OF LICENSE *(e.g., Broad Scope, Private Practice Medical, etc.)*	**LICENSE NUMBER**	**THIS ITEM NUMBER**
BROAD SCOPE	20-29-22	

ABNORMAL OCCURRENCE	FOLLOW-UP REPORT	THE PATIENT WAS NOTIFIED	DATE OF EVENT
[ ] YES [X] NO	[ ] YES [X] NO	[X] YES [ ] NO	Oct. 16, 1996

DATE OF THIS REPORT: JAN. 13, 1997

[ ] SODIUM IODINE, I-125 OR I-131, > 30 MICROCURIES
- [ ] WRONG PATIENT
- [ ] WRONG RADIOPHARMACEUTICAL
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20% AND DIFFERENCE EXCEEDS 30 MICROCURIES

[ ] THERAPEUTIC RADIOPHARMACEUTICAL DOSE, OTHER THAN I-125 OR I-131
- [ ] WRONG PATIENT
- [ ] WRONG RADIOPHARMACEUTICAL
- [ ] WRONG ROUTE OF ADMINISTRATION
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%

[ ] STEREOTACTIC RADIOSURGERY (GAMMAKNIFE)
- [ ] WRONG PATIENT
- [ ] WRONG TREATMENT SITE
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY MORE THAN 10%

[ ] TELETHERAPY
- [ ] WRONG PATIENT
- [ ] WRONG MODE OF TREATMENT
- [ ] WRONG TREATMENT SITE
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY MORE THAN 10% IF THERE ARE 3 OR FEWER FRACTIONS PRESCRIBED; OR WHEN WEEKLY CALCULATED ADMINISTERED DOSE EXCEEDS PRESCRIBED DOSE BY > 30%; OR WHEN CALCULATED TOTAL ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%.

[ ] BRACHYTHERAPY
- [ ] WRONG PATIENT
- [ ] WRONG RADIOISOTOPE
- [X] WRONG TREATMENT SITE
- [ ] LEAKING SOURCE
- [ ] ONE OR MORE SOURCES NOT REMOVED AT END OF TREATMENT
- [ ] CALCULATED ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%

[ ] DIAGNOSTIC RADIOPHARMACEUTICAL DOSE, OTHER THAN QUANTITIES THAT EXCEED 30 MICROCURIES OF I-125 OR I-131, OR BOTH, WHEN THE PATIENT DOSE EXCEEDS 5 REM EFFECTIVE DOSE EQUIVALENT OR 50 REM ORGAN DOSE AND INVOLVES:
- [ ] WRONG PATIENT
- [ ] WRONG RADIOPHARMACEUTICAL
- [ ] WRONG ROUTE OF ADMINISTRATION
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSAGE

ABSTRACT *(Include the cause of the misadministration, contributing factors, and licensee corrective action. May be continued on the reverse side.)*

See Attached.

RTMENT FOR PUBLIC HEALTH

CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
FRANKFORT 40621-0001

MEMORANDUM

TO: Incident File

FROM: Vicki D. Jeffs, Supervisor
Radioactive Materials Unit

SUBJECT: Misadministration at University of Louisville
KRML No. 202-029-22

DATE: January 9, 1997

On October 16, 1996 a telephone notification was received from Mike Kelly, Radiation Safety Officer (RSO), of this facility regarding a potential misadministration. A written report, dated October 30, 1996 was received from Mr. Kelly on November 4. An investigation was performed on November 19, 1996.

EVENT INVESTIGATION

The following individuals were interviewed during the investigation:

Mike Kelly, RSO
Peter Almond, Ph.D., Chairman RSC and Director
Chris Naville, Nurse Coordinator, Oncology
Dave Wilson, Clinical Physicist
Dr. Mark Cornett, Radiation Oncology/Authorized User
Dr. Qamar, Resident
Mary Auter, Nurse

Based on these interviews, the following scenario appears to have occurred.

On October 14, 1996 at approximately 6:00 p.m. a female patient was implanted with 124 mCi Cs-137 (sealed brachytherapy sources) and 11.3 mCi Ir-192 (a total of 5 ribbons - 3 containing 5 seeds and 2 with 3 seeds each). A styrofoam cup was placed at the end of the catheter to assist in holding the sources in place. A check of the patient on 6:00 p.m. on October 15 indicated the sources were in place according to Dr. Cornett. A nurse noticed tape on the patient's thigh at approximately midnight on October 15 but did not know this was not the norm for this procedure, according to the physician's notes. During rounds on the following morning (Oct. 16), two of the ribbons were observed to be out of the patient and on her thigh.

The RSO was notified by Dr. Almond at approximately 10:00 a.m. on October 16 that the implant site had been disturbed. A search for the ribbons ensued. All ribbons were found in the room and accounted for. (The cesium sources had not been dislodged.) The sources were re-implanted into the patient to make up the unreceived dose.

Film badges for the 3 nursing personnel entering the room were sent for processing. The highest reading was 10 millirems. Calculations were performed by the clinical physicist for the dose to the thigh and the difference in the prescribed and received dose to the intended area. The difference in the prescribed vs. received dose was 3485 rads prescribed vs. 3380 rads received. This resulted in an underdose of approximately 3 percent. This was not deemed to be a misadministration. The underdose was eliminated by re-implanting the sources. However, the unintended dose to the thigh did result in a misadministration. The dose to the thigh was calculated to be 192 rads. This calculation assumed the ribbons were on the patient's leg for approximately 7 hours. This time was based on the observation of the tape on the patient's thigh at midnight and the time of the morning rounds by the resident physician.

The patient and referring physician were notified. Examination of the patient during follow-up visits did not reveal any skin reaction of the area receiving the unintended dose.

CONTRIBUTING EVENTS

The attending nurse was asked during the interview if she had received training prior to working with implant patients. She stated she had. Training records were reviewed and this training had been documented. However, this individual stated that although she had been shown some brachytherapy sources, she had not been trained in recognizing a "fishing line" type source (i.e., Ir ribbons). This is considered as a contributing factor in this misadministration and the licensee is being cited for inadequate training in accordance with 902 KAR 100:073, Section 42.

Patient intervention was also a contributing factor to this misadministration.

CORRECTIVE ACTIONS BY LICENSEE

The licensee RSO stated in the submitted written report that retraining of nursing personnel would be conducted regarding the recognition of all types of brachytherapy sources used at the facility. The authorized user stated a review would be conducted of brachytherapy procedures to determine if the use of rubber caps on the catheter could be used in place of the styrofoam cup.

The physicist stated that the rubber caps could cause other problems when pushing the cap on the end of the catheter since this pressure could result in the catheter being mispositioned.

According to a written report submitted by the authorized user, all administering physicians were instructed to inform the appropriate nursing personnel of the details of each implant case on an individual basis in order to assist the personnel in the recognition of dislodged sources.

CONCLUSION

Inadequate training and patient intervention appeared to contribute to this event. No adverse effect was noted for the patient. Although the licensee stated corrective action had been taken, an NOV has been issued. Upon receipt of written verification of corrective action, the case will be considered closed.