RI - DNMS Licensee Event Report
Disposition

Licensee: St. Francis Hospital and Medical Center

Event Description: ~~Medical~~ Event - other - patient intervention

License No:	06-14734-01	Docket No:	0300246	MLER-RI:	2007-004
Event Date:	02/06/07	Report Date:	02/06/07	HQ Ops Event #:	43147

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [ ] Other
- [ ] 10 CFR 30.50 Report
- [x] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [ ] Immediate Site Inspection
- [✓] Special Inspection
- [ ] Telephone Inquiry
- [ ] Preliminary Notification/Report
- [X] Information Entered in RI Log
- [ ] Report Referred To:

Inspector/Date
Inspector/Date: Weidner 2/20-21-2007
Inspector/Date

- [ ] Daily Report
- [ ] Review at Next Inspection

3. REPORT EVALUATION

- [✓] Description of Event
- [✓] Levels of RAM Involved
- [✓] Cause of Event
- [✓] Corrective Actions
- [✓] Calculations Adequate
- [ ] Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

- [ ] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality
- [ ] Deliberate Misuse w/Exposure > Limits
- [ ] Pkging Failure>10 rads/hr or Contamination>1000x Limits
- [ ] Large# Indivs w/Exp>Limits or Medical Deterministic Effects
- [ ] Unique Circumstances or Safeguards Concerns

If any of the above are involved:

- [ ] Considered Need for IIT
- [ ] Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

- [✓] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report:
- [ ] Medical Consultant Determined Event Directly Contributed to Fatality
- [ ] Device Failure with Possible Adverse Generic Implications
- [ ] HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

Event due to patient intervention - Not Medical Event

☐ Non-Public

☑ Public-SUNSI REVIEW COMPLETE

Inspector Signature: [signature] Date: 4.6.07

Branch Chief Initials: [signature] Date: 4/6/07

Location of File: G:\Reference\Blank Forms\LER FORM.wpd

Rev. 02/25/05

SAINT FRANCIS
Hospital and Medical Center

114 Woodland Street
Hartford, Connecticut
06105-1299

860 714-4000

February 12, 2007

Attn: Ms. Tara Weidner
Medical Branch
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License No. 06-00854-03 Saint Francis Hospital and Medical Center
Docket No. 030-01246
Reference No. 06-14734-01

Dear Ms. Weidner,

Herewith we are reporting a medical event occurring during a patient treatment using our LDR Selectron afterloader unit. According to §35.3045 an event that results from patient intervention is not reportable. However, when I spoke to Mr. Willie Lee of your office on February 6th I was told to report this event. Therefore, I called the NRC operations center (301-951-0550) as requested and gave an oral report to Mr. John MacKinnon in the afternoon of February 6th and I am following up with the written details of the incident.

The patient is a fifty nine year old lady on treatment for a stage II cervical cancer. She has other medical problems including chronic alcoholism. The patient was admitted on February 5, 2007 for a planned LDR brachytherapy with a Fletcher-Suit (tandem and ovoids). She had been cleared medically for anesthesia the week prior. On February 5, she underwent placement of the applicator by both the GYN Oncologist and Radiation Oncologist without a problem. X-rays were taken in the operating room confirming good placement of the applicator.

A computerized treatment plan was prepared and the radiation oncologist and authorized user, Dr. Eric VanRooy, prescribed a dose of 2046.5 cGy to be delivered at dose rate 52.5 cGy/h to average point A. Our plan showed that nine (9) Cs-137 sources in three (3) catheters would cover very well the patient target volume. The total treatment time was calculated to be thirty nine (39) hours. The plan was done by Lucy Nedialkova, Ph.D., checked by Dr. Ellen Wilcox, authorized medical physicist, and approved by Dr. VanRooy.

The LDR treatments in our hospital are given in room 8100 of the main building. Before treatment the LDR unit and all radiation monitors, interlocks and camera systems were tested and a film was taken of the planned treatment showing positions and numbers of sources which were to be used during the treatment. A radiation monitor is suspended over the patient bed and a camera shows this monitor as well as the patient at the nurses' station. Also if the door is opened or any other fault occurs with the unit an alarm sounds at the nurses' station. The nursing staff was instructed that this patient had a complex medical history and that they should be particularly vigilant. The patient had been prescribed pain medication PRN as well as Ativan PRN by the admitting physician particularly in light of her alcohol history and the concern of her going into withdrawal. The patient was evaluated throughout the night by the nursing staff.

The patient treatment started at 12:35PM (February 5, 2007). Dr. Ellen Wilcox and Dr. VanRooy carried pagers and were on call.

Dr. Diana Leblanc, the gynecology resident on duty checked on the patient at 6:21AM on February 6, 2007. She examined the patient and confirmed good placement of the applicator. Her evaluation was documented in the chart. 16.09 hours of the treatment had been delivered at that time.

Dr. VanRooy checked on the patient at 7:17AM, 56 min. later. He found that the patient was disoriented and agitated. The patient had pulled out the applicator 4 cm below the intended placement. There was no bleeding.

Dr. VanRooy contacted the admitting physician, Dr. Scott Kamelle, and they decided to stop the treatment and remove the applicator. The applicator was removed by Dr. VanRooy with the assistance of a nurse. The Chief Physicist, Dr. Ellen Wilcox was informed at 8 AM and a radiation survey of the patient and the LDR unit were done and the unit shut down.

A calculation of the actual dose delivered in 16.09 hours was done and found to be 844.5 cGy to the intended site. The printout from the afterloader unit indicates no further interruptions of the treatment in the time between 6:21AM and 7:17AM and there was no one other than the patient in the room. Since the Fletcher-Suit applicator is solidly packed in and it is impossible to slip out on its own, only the patient herself would have pulled it out. However, since she was heavily sedated she has no recollection having dislodged the applicator.

The entire applicator assembly had been moved down 4 cm. At this position of the applicator the estimation based on the films and the clinical picture showed that the tandem and ovoids and hence the active sources were in the vagina and not in the uterus and near the cervix which was the planned position. Assuming in the worst case scenario that the applicator was in this wrong position for the full 47 minutes between 6:30 AM and 7:17 AM we calculated the dose delivered to the upper vagina and lower vagina.

Upper vagina: If the full 39 hours would have been delivered the closest point to the ovoids would have received 2926.56 cGy. With the applicator being in the correct position for 16 hours and the ovoids shifted for 1 hour this point now received 1225 cGy.

For the lower vagina where the ovoids were after the shift, this position would have received 465 cGy from the full 39 hours treatment but received only 267 cGy from the 16 hour treatment and the one hour with the shifter position.
Therefore all areas of the vagina were actually underdosed relative to the intended dose.

The patient was examined by GYN oncologist. By palpable examination he found that there is no vaginal laceration.

The patient was discharged home later that day in stable conditions. The patient and the family were informed about the event. The VNA was also notified to keep a close eye on the patient for any possible acute reaction. The patient is scheduled for follow up on February 13, 2007 for further evaluation and treatment plans.

Based on the estimated dose to the vagina we would not anticipate any acute or long term untoward reaction to the patient.

Yours truly,

Ellen Wilcox

Ellen Wilcox, Ph.D., FCCPM, FAAPM
Chief Medical Physicist and Radiation safety Officer
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cc: Amit Mody, MD, Executive Vice President and COO
Mary Inguanti, Vice President, Operations and Quality

SAINT FRANCIS
Hospital and Medical Center

114 Woodland Street
Hartford, Connecticut
06105-1299

860 714-4000

February 13, 2007

Attn: Ms. Tara Weidner
Medical Branch
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License No. 06-00854-03 Saint Francis Hospital and Medical Center
Docket No. 030-01246
Reference No. 06-14734-01

Dear Ms. Weidner,

This is a follow up to my recent report of the medical event during which a patient under treatment using our LDR Selectron afterloader unit pulled out the applicator.
The patient was seen in follow up today by the radiation oncologist, Dr. Eric VanRooy. She states that she indeed pulled out the applicator since it was too uncomfortable and she is adamant that she refuses further treatment involving insertion of applicators.

Yours truly,

Ellen W. Wilcox

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Hospital	Event Number: 43147
Rep Org: ST. FRANCIS HOSPITAL, HARTFORD, CT Licensee: ST. FRANCIS HOSPTIAL, HARTFORD, CT Region: 1 City: HARTFORD State: CT County: HARTFORD License #: 06-00854-03 Agreement: N Docket: NRC Notified By: E. WILCOX HQ OPS Officer: JOHN MacKINNON	Notification Date: 02/06/2007 Notification Time: 13:49 [ET] Event Date: 02/06/2007 Event Time: 07:00 [EST] Last Update Date: 02/06/2007
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE	Person (Organization): WILLIAM COOK (R1) GREG MORELL (NMSS)

Event Text

MEDICAL EVENT

A patient was being treated for cancer of the cervix. The planned total dose to the cervix was to be 2046.5 cGy, over a 39 hour time period. The licensee was using an LDR Selectron Afterloader. Nine cesium-137 sources, activity of each source 16.7 millicuries, were used in the afterloader. The patient started treatment on 02/05/07 at 1235 EST. Today, 02/06/07, between the hours of 0630 - 0717 EST the patient pulled the applicator out approximately 4 centimeters.

The patient was given the correct dose to the cervix for 16.09 hours for a total dose of 844.5 cGy. The patient was given an incorrect dose to the vaginal area for between 30 - 60 minutes. The total dose to the incorrect area is between 50 - 200 (Max) cGy. This incident was not harmful to the patient. The patient's doctor was notified of this incident. The patient will not be retreated.

A "Medical Event" may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.