

RI - DNMS Licensee Event Report Disposition

Licensee: University of Virginia Hospital
 Event Description: Medical Event - Patient received underdose
 License No: 45-00034-26 Docket No: 030032916 MLER-RI: 2007-001
 Event Date: 02/04/07 Report Date: 02/09/07 HQ Ops Event #: 43145

1. REPORTING REQUIREMENT

<input type="checkbox"/>	10 CFR 20.1906 Package Contamination	<input type="checkbox"/>	10 CFR 30.50 Report
<input type="checkbox"/>	10 CFR 20.2201 Theft or Loss	<input checked="" type="checkbox"/>	10 CFR 35.3045 Medical Event
<input type="checkbox"/>	10 CFR 20.2203 30 Day Report	<input type="checkbox"/>	License Condition
<input type="checkbox"/>	Other _____		

2. REGION I RESPONSE

<input type="checkbox"/>	Immediate Site Inspection	Inspector/Date	
<input type="checkbox"/>	Special Inspection	Inspector/Date	
<input type="checkbox"/>	Telephone Inquiry	Inspector/Date	
<input type="checkbox"/>	Preliminary Notification/Report	<input type="checkbox"/>	Daily Report
<input checked="" type="checkbox"/>	Information Entered in RI Log	<input type="checkbox"/>	Review at Next Inspection
<input type="checkbox"/>	Report Referred To: _____		

3. REPORT EVALUATION

<input checked="" type="checkbox"/>	Description of Event	<input checked="" type="checkbox"/>	Corrective Actions
<input checked="" type="checkbox"/>	Levels of RAM Involved	<input checked="" type="checkbox"/>	Calculations Adequate
<input checked="" type="checkbox"/>	Cause of Event	<input checked="" type="checkbox"/>	Additional Information Requested from Licensee

62.66 mgy Ra eq of Cs-137

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

N/A

<input type="checkbox"/>	Release w/Exposure > Limits	<input type="checkbox"/>	Deliberate Misuse w/Exposure > Limits
<input type="checkbox"/>	Repeated Inadequate Control	<input type="checkbox"/>	Pkging Failure > 10 rads/hr or Contamination > 1000x Limits
<input type="checkbox"/>	Exposure 5x Limits	<input type="checkbox"/>	Large# Indivs w/Exp > Limits or Medical Deterministic Effects
<input type="checkbox"/>	Potential Fatality	<input type="checkbox"/>	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)

<input checked="" type="checkbox"/>	Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
<input type="checkbox"/>	Medical Consultant Used-Name of Consultant/Date of Report: <u>Subir Nag, MD, 3-15-07</u>
<input type="checkbox"/>	Medical Consultant Determined Event Directly Contributed to Fatality
<input type="checkbox"/>	Device Failure with Possible Adverse Generic Implications <i>N/A</i>
<input type="checkbox"/>	HQ or Contractor Support Required to Evaluate Consequences <i>N/A</i>

6. SPECIAL INSTRUCTIONS OR COMMENTS

Sources = Amersham Searle model CDC Series

Non-Public Inspector Signature: [Signature] Date: 4/10/07
 Public-SUNSI REVIEW COMPLETE Branch Chief Initials: [Signature] Date: 5/8/07

UNIVERSITY
of VIRGINIA



ENVIRONMENTAL HEALTH *and* SAFETY
Special Materials Handling Facility

February 19, 2007

Ms. Sandra Gabriel
U.S. Nuclear Regulatory Commission
Region I, Nuclear Material Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Ms. Gabriel,

Attached you will find a summary report regarding the medical event that occurred at the University of Virginia Medical Center under our Broad By-product License #45-00034-26. This event (number 43145) was reported to the Operations Center on February 5, 2007.

In response to this event, the Radiological Physics and Radiation Oncology staffs have thoroughly reviewed their procedures and have revised several. A number of meetings and in-services have been held with key individuals to review procedures and the corrective measures that have been implemented. I believe that this event was an isolated one and that the prompt investigation that was conducted by staff and subsequent implementation of corrective measures will prevent recurrence of such an event.

If you require any additional information, please contact me or my staff.

Sincerely,

Ralph Allen, RSO

RECEIVED
REGION I
2007 FEB 20 AM 10:40

Date: 19 February 2007

To: Sandra Gabriel, PhD, Sr. Health Physicist
U.S. Nuclear Regulatory Commission
Region I, Nuclear Material Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

From: Stanley H. Benedict, PhD, DABR
Director of Radiological Physics
University of Virginia Health System, Dept. of Radiation Oncology

Subj: Written Report in accordance with NRC 35.3045 for Medical Event discovered on February 4th, 2007 at the University of Virginia Health System.

Licensee's Name: University of Virginia

Prescribing Physician: Dr. Bernard F. Schneider, Referring Radiation Oncologist, UVA

Brief Description of Event:

The patient identified in the annotated version of this report was scheduled for a routine Fletcher-Suit (F-S) gynecological applicator boost using Cs-137 low dose rate (LDR) brachytherapy. On February 2, 2007 the patient had the F-S device implanted in the OR followed by a simulation with dummy seeds for treatment planning. Based on the simulation films a plan was designed for which the LDR Written Directive (WD) specified 30 Gy to "Point A" and requiring a total of 48.5 hours. Upon removal of the implant at the allotted time it was discovered by the physician on-call that the source insert in the tandem was not readily retrievable. The physician on-call immediately contacted both the attending physician and on-call physicists, and it was determined that the proper response was to remove the entire tandem and place it with the ovoids in the transporter lead container. A physicist arrived within 30 min and confirmed that the insert in the tandem was too short, but that the sources were all accounted for, and returned them to the safe. An investigation ensued to determine if this was indeed a medical event, and the USNRC was notified of this situation within 24 hours of discovery on February 5, 2007, and a follow-up inspection was performed by the USNRC on Monday February 12, 2007.

Why the Event Occurred

The physicist loading the tandem for the F-S applicator utilized a plastic radioactive source carrier insert that was 4 cm shorter than the required 24 cm. Although the Cs-137 cylinder sources within the carrier tube were loaded in their correct relative positions and these sources had the correct activity levels required by the WD and its associated treatment plan, they were not in an insert long enough for proper positioning. The sources in the right and left ovoids were correctly loaded and not affected by the tandem insert.

The physicist followed the current checklist for preparing an implant applicator, and this checklist did not have a step for verifying the proper length of the plastic insert. The physician loading the insert was also not aware that the insert was too short. The discovery came from the physician responsible for removal of the implant, since a source insert that is too short is very difficult to remove from the tandem.

Effect on the Individual receiving the LDR Administration

During treatment the tube insert did not fully reach the distal end of the metallic tandem tube. Therefore, a portion of the area treated was displaced from the region specified in the WD as Point A. The prescription in the WD was for Point A to receive 30 Gy, however an evaluation of the actual delivered dose determined that there was an underdosage, and approximately 7.7 Gy was delivered. This difference in dose delivery meets the requirement for reporting as a medical event as described in NRC regulation 35.3045.

A strategy for correcting for the underdosage from this implant is currently under evaluation. The doses delivered to other areas due to the incorrect positioning of the insert have been assessed by the attending radiation oncologist and they are not considered to be clinically significant. The planned/actual doses have been provided previously and they are also tabulated below.

	Calculated Point	Planned Dose (cGy)	Actual Dose Received (cGy)
1	A Right	2957	728
2	A Left	3043	807
3	B Right	657	407
4	B Left	707	380
5	Rectum 1	2074	2677
6	Rectum 2	1857	1411
7	Rectum 3	930	2472
8	Bladder	2982	1165
9	Vaginal Mucosa 1	411	1484
10	Vaginal Mucosa 2	265	1414

Actions Taken to Prevent Recurrence

- 1) An in-service was held for Radiation Oncology Department dosimetrists, physicists, physicians to discuss the event and provide specific instructions to prevent future occurrences. For future implants the physician loading the patient will check that the source carrier length is a minimum of 24 cm.
- 2) In the source preparation room, a plastic sheet with a 24 cm long black stripe was affixed to the prep table, which allows a quick length check by physicists preparing radioactive insert holders.
- 3) The handle of the wheeled source safe used to transport the loaded inserts to the patient room will also have a 24 cm stripe to be used by the personnel loading the patient.

4) The LDR procedure was updated and two steps were added. One new step on the checklist requires a carrier insert minimum 24 cm length confirmation. The other new step requires that the physician performing the source loading visually observe that the white plastic spacer cap extends out about 0.3 cm from the tandem tube. This cap extension indicates that the tube is fully inserted, and the extension is accommodated in the screw-on-cap to the tandem tube.

5) All old or cut up plastic source carrier tube inserts in use in the source prep room have been replaced by new carriers of correct length, and in the future any insert modified to less than 24 cm will be discarded after use.

Rationale for determining that this has been a single event

In our investigation by Radiation Oncology staff (including physicians, physicists, and dosimetrists) it has been determined that this was entirely likely to have been a single and isolated event. Had such an event occurred before, it would have been discovered in the same way this one was, which was by the difficulty/impossibility in the removal of the insert tube into the tandem.

This issue has been fully discussed at a special assembly of the departmental Quality Improvement Committee, and the Committee also agreed that it is highly unlikely that this particular event had ever occurred before. The committee was alerted to the corrective actions underway and agreed they were satisfactory to prevent a recurrence of this medical event.

Patient, Physician & Referring Physician Were Notified within 24 hours.

The attending radiation oncologist notified the patient and the referring GYN service on Monday February 5, 2007, within 24 hours of the occurrence.

Hospital	Event Number: 43145
Rep Org: UNIVERSITY OF VIRGINIA HOSPITAL Licensee: UNIVERSITY OF VIRGINIA Region: 1 City: CHARLOTTESVILLE State: VA County: License #: 45-00034-26 Agreement: N Docket: NRC Notified By: DEBBY STEVA HQ OPS Officer: JOHN MacKINNON	Notification Date: 02/05/2007 Notification Time: 13:56 [ET] Event Date: 02/04/2007 Event Time: 18:00 [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) MICHELE BURGESS (NMSS)

Event Text

<p>MEDICAL EVENT - PATIENT RECEIVED AN UNDERDOSE</p> <p>"A FS (Tandem and ovoid) device was loaded into a patient for Cs-137 brachytherapy of the cervix on Friday Feb 2, 2007. The written directive was for 3000 cGy to Pt A in 48.5 hours. Upon removal of the device on Sunday Feb 4, 2007 at approximately 5PM it was observed that the plastic tube used to hold the Cs sources in the tandem was not of the standard length: it was short by approximately 4 cm. The consequence of this would be that the tandem sources would not have been in the position planned. The patient received an underdose to Point A of 760 cGy vs. the 3000 cGy that had been prescribed. Follow-up treatment is planned to correct for this underdose. Clinically, according to the physician, the dose the patient received to distal vaginal would not be expected to cause adverse reactions. "</p> <p>* * * UPDATE FROM FLANNERY (FSME) TO HUFFMAN VIA E-MAIL AT 1218 EST ON 2/06/07 * * *</p> <p>This event has been reviewed by the NRC medical review committee and determined to be a reportable medical event.</p> <p>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.</p>
