RI - DNMS Licensee Event Report
Disposition

Licensee: Cooper Health System

Event Description: Medical Event - Underdosage

License No: 29-08285-01 | Docket No: 0303197 | MLER-RI: 2006-049

Event Date: 11/09/06 | Report Date: 12/19/06 | HQ Ops Event #: 43057

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

- [x] Immediate Site Inspection — identified during routine inspection — Inspector/Date: Gabriel 12/18+20/06 1/5/07
- [ ] Special Inspection — Inspector/Date:
- [ ] Telephone Inquiry — Inspector/Date:
- [ ] Preliminary Notification/Report
- [x] Information Entered in RI Log
- [ ] Report Referred To:
- [ ] Daily Report
- [ ] Review at Next Inspection

3. REPORT EVALUATION

- [x] Description of Event
- [x] Levels of RAM Involved — in terms of dose
- [x] Cause of Event
- [x] Corrective Actions
- [x] Calculations Adequate
- [x] Additional Information Requested from Licensee — source activity on event date, serial #'s, more info about event description, cause, corrective actions

4. NA 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)

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

pending decision

6. SPECIAL INSTRUCTIONS OR COMMENTS

HDR unit = Nucletron Model 105.999 serial # 31469; HDR source = Nucletron Model 105.002, manuf. by ~~AEA Technology, serial # D36B-0063~~

[x] Non-Public — Inspector Signature: Sandra Sabrud — Date: 1/6/07

[ ] Public-SUNSI REVIEW COMPLETE — Branch Chief Initials: — Date: 1/8/07

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

Rev. 02/25/05

Unit = Nucletron 105.999, S/N 31469
Source = Nucletron 105.002, manuf by AEA Technology, S/N D36B-0063
Source activity = 6.405 Ci on date of medical event

Hospital	Event Number: 43057
Rep Org: COOPER HEALTH SYSTEM Licensee: COOPER HEALTH SYSTEM Region: 1 City: CAMDEN State: NJ County: License #: 29-08285-01 Agreement: N Docket: NRC Notified By: ED GOLDSCHMIDT HQ OPS Officer: JOHN MacKINNON	Notification Date: 12/19/2006 Notification Time: 14:41 [ET] Event Date: 11/09/2006 Event Time: 11:00 [EST] Last Update Date: 12/20/2006
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE	Person (Organization): RAY POWELL (R1) GREG MORELL (NMSS)

Event Text

DISCOVERED THAT A PATIENT RECEIVED AN UNDERDOSAGE

"During a routine NRC inspection on 12/18/06 Sandra Gabriel Ph.D, Senior Health Physicist from Region I, discovered a medical event that occurred on 11/9/06 involving a HDR (35.600) treatment.

"On 11/9/06 an HDR treatment patient received a dose of 1.37 Gy to Point A when the prescribed intended dose was 6.0 Gy.

"The following scenario lead to the medical event.

"A 6.0 cm tandem was inserted into the patient, however, the Authorized User asked the Authorized Medical Physicist to treat only a length of 4.0 cm to spare excess dose to normal structures. After the patient was treated, the Authorized Medical Physicist told the Authorized User he miscalculated the appropriate treatment length and what he thought was 2.0 cm from the end of the tandem was actually 20 cm from the tip of the tandem. The Authorized User and Authorized Medical Physicist calculated where 20 cm was, and this point was in fact outside of the patient's body, thus the patient only received dose from the ring portion of the applicator, resulting in a dose of 1.37 Gy to point A of the prescription plan.

"Since this dose was subtherapeutic, the Authorized User added an extra HDR treatment (during the course of treatments) and the patient received a total dose to point A of 31.37 Gy which was within 20% of the original intended total dose. The patient was made aware of the extra treatment that was necessary because of the under dosage on 11/9/06.

"A full written report will follow within 15 days as required by 10 CFR 35.3045."

* * UPDATE FROM FLANNERY (FSME) TO KOZAL AT 1213 ON 12/20/06 * * *

This event has been reviewed by the NRC medical review committee and determined to be a reportable medical event.

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.

The Cooper Health System
Robert Wood Johnson Medical School at Camden
One Cooper Plaza
Camden, NJ 08103

NRC License number 29-08285-01

December 28, 2006

Sandra Gabriel, Ph.D.
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Region I, Medical Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
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King of Prussia, PA 19406-1415
Fax Number: 610-337-5269.

Dr. Gabriel,

This written report is being submitted to satisfy 10 CFR 35.3045 (d). There was a Medical Event in our Radiation Oncology Department on 11/9/2006 that was discovered during a routine NRC inspection on 12/18/2006. If you have any questions in regards to this written report please contact our Radiation Safety Officer Edward Goldschmidt, MS, DABMP at 856-342-2723 or by e-mail at goldschmidt-ed@cooperhealth.edu.

Sincerely,

Jeffrey Yarmel
Senior Executive Vice President and Chief Operating Officer
The Cooper Health System
Robert Wood Johnson Medical School at Camden
One Cooper Plaza
Camden, NJ 08103

Written Report to satisfy 10 CFR 35.3045 (d)

(i) The licensee's name: The Cooper Health System – Robert Wood Johnson Medical School at Camden

(ii) The name of the prescribing physician: Clarissa Henson, MD

(iii) A brief description of the event:

A patient with cervical cancer was prescribed a total dose of 30.0 Gy to point A by the Authorized User on 10/30/2006. The prescribed dose was to be delivered with a High Dose Rate (HDR) remote Afterloader device. The written directive completed on 10/30/2006 prescribed 6.0 Gy per fraction with a total number of fractions equal to 5.0. The written directive also documented that a-ring and 4.0 cm tandem length was to be utilized for the treatments. The patient was treated with 6.0 Gy to point A on 10/30/2006 using the written directive parameters specified.

On 11/9/2006 the Authorized User changed the tandem length to 6 cm for clinical reasons. This was the second fraction of the treatment course. After the 6.0 cm tandem was inserted into the patient, the Authorized User (AU) asked the Authorized Medical Physicist (AMP) to treat only a length of 4.0 cm to spare excess dose to normal structures. After the patient was treated, the Authorized Medical Physicist told the Authorized User that he did not program the appropriate treatment length in the treatment console in an attempt to offset 2.0 cm. What the Authorized Medical Physicist thought was 2.0 cm from the tip of the tandem was actually 20 cm from the tip of the tandem. The Authorized User and Authorized Medical Physicist calculated where 20 cm from the tip of the tandem was, and those dwell points were in fact outside of the patient's body. Thus the patient only received dose from the ring portion of the applicator, resulting in a dose of 1.37 Gy to point A of the prescription plan.

The patient on 11/13/2006, 11/16/2006, and 11/20/2006 received fractions of 6.0 Gy and thus received 25.37 Gy to point A from the first 5 fractions. Since this dose was sub-therapeutic, the Authorized User added an extra HDR treatment fraction of 6.0 Gy on 11/27/2006 and the patient received a total dose to point A of 31.37 Gy which was within 20% of the original intended total dose of 30.0 Gy.

The 4 cm tandem length was used for all the fractions except that of the medical event. Treatment planning was performed for each 4 cm tandem length treatment and proper verification of treatment details were confirmed prior to each treatment.

(iv) Why the event occurred:

The medical event occurred because treatment planning was not performed after the 6.0 cm tandem was inserted into the patient. Once the 6 cm tandem was placed in the patient a new treatment plan should have been performed. The new treatment plan for the 6 cm tandem length would have allowed a comparison and verification of the treatment plan printout (including source length) with that of the treatment console data printout. This necessary verification was not performed.

(v) The effect, if any, on the individual(s) who received the administration:

As a result of the brachytherapy source lying outside of the patients internal organs, radiation was delivered to the patient's inner thigh (the skin nearest to the tandem applicator). The dose to the skin was calculated to be 0.468 Gy. For detailed calculation, please refer to the attachment "**DOSE EVALUATION FOR THE MEDICAL EVENT OF 11/9/06".**

(vi) What actions, if any, have been taken or are planned to prevent recurrence:

To prevent recurrence, the following actions are planned:

1. Modification in effective tandem length will only be made in the treatment planning system. If a modification in tandem length is to be made after the insertion, it will be made in the treatment planning computer, not in the treatment console, as planning will checked and verified by an independent calculation.

2. An immediate and annual in-service will be provided by the Radiation Safety Officer to the Authorized Users and Authorized Medical Physicists in regards to the 10 CFR 35.3045 Report and notification of a medical event requirements.

3. Written directives will be audited quarterly by the Radiation Safety Officer, Authorized Medical Physicist, and Authorized User.

4. An independent Radiation Oncology physics consultant, who is an Authorized Medical Physicist, will be hired to audit and make recommendations to improve the Radiation Oncology radioactive material program.

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

The patient was informed that an additional fractionated dose would be required to complete her radiation treatments, but was not given the details of the single fraction under-dosage. Given the patient's fragile mental state, history of drug abuse and noncompliance with therapy; the Authorized User believed it would be harmful to the patient to explain the details of the single fraction under-dosage. The Authorized User provided the patient's referring physician the details required by 10 CFR 35.3045 (e) on 12/21/2006.