RI - DNMS Licensee Event Report Disposition

Licensee: United Hospital Center

Event Description: Report of Medical Event

License No: 47 01458-01 Docket No: 030 03375 MLER-RI: 2006-016

Event Date: 04-18-06 Report Date: 4-19-06 HQ Ops Event #:

1. REPORTING REQUIREMENT

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

2. REGION I RESPONSE

	Immediate Site Inspection	Inspector/Date	RAGLAND/4/25/06
	Special Inspection	Inspector/Date	
	Telephone Inquiry	Inspector/Date	
	Preliminary Notification/Report		Daily Report
X	Information Entered in RI Log		Review at Next Inspection
	Report Referred To:		

3. REPORT EVALUATION

X	Description of Event	X	Corrective Actions
	Levels of RAM Involved		Calculations Adequate
X	Cause of Event		Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

N/A	Release w/Exposure > Limits	N/A	Deliberate Misuse w/Exposure > Limits
	Repeated Inadequate Control		Pkging Failure>10 rads/hr or Contamination>1000x Limits
	Exposure 5x Limits		Large# Indivs w/Exp>Limits or Medical Deterministic Effects
↓	Potential Fatality	↓	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	Subir Nag June 2, 2006
—	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

☐ Non-Public

☒ Public-SISP REVIEW COMPLETE

Inspector Signauture: Rodney C. Ragland Date: 6/9/06

Branch Chief Initials: Date: 6/14/06

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

Reviewed Both Documents

Rev. 02/25/05

UNITED HOSPITAL CENTER Post Office Box 1680 Clarksburg, West Virginia 26302-1680 Telephone 304/624-2574

May 2, 2006

U.S. Nuclear Regulatory Commission, Region II
Material Licensing/Inspection Branch
Sam Nunn Atlanta Federal Center, Suite 23T85
61 Forsyth Street, SW, Atlanta, GA 30303-8931

Re: NRC License #47-01458-01; report of a medical event

On April 19, 2006, we notified the NRC Operations Center of a medical event we had discovered on April 18, 2006. The written report of that event is attached.

If you have any questions or require additional information, contact our Radiation Safety Officer, James Israel, at (304) 624-2574.

Thank you.

Sincerely,

Michael Tillman
Chief Operating Officer

May 2, 2006

Report of Medical Event
Discovered on April 18, 2006

United Hospital Center
Clarksburg, West Virginia
NRC License #47-01458-01

United Hospital Center, Clarksburg, WV
Report of Medical Event

May 2, 2006

This report is submitted in accordance with 10 CFR 35.3045. It describes a medical event that we reported by telephone to the NRC Operations Center on April 19, 2006.

1. **Licensee's name:** United Hospital Center

2. **Name of the prescribing physician:** Michael A. Stewart, M.D.

3. **Description of the event:**

   On April 18, 2006, we were performing the treatment planning for the second in a series of six radiation treatments to a patient's cervix. The treatment was to be delivered with our high-dose-rate remote afterloader. During the course of that treatment planning session, we noticed that the incorrect magnification factor had not been entered into the computer. That error had caused the computer to calculate a treatment time that was slightly greater than twice what it should have been.

   A review showed that this patient (Patient A) had received an average dose to the prescription points of 1,041 centigray (cGy) rather than the prescribed 500 cGy in her first treatment, which had been performed on April 11, 2006.

   Further review showed that we made a similar error in the treatment planning for another patient (Patient B), who had received her first treatment several hours earlier, on the morning of April 18, 2006. That patient received an average dose to the prescription points of 1,058 cGy rather than the prescribed 500 cGy.

   The prescribing physician decided to alter the written directive for each of the patients. The original directive was for 6 treatments x 500 cGy per treatment for a total dose of 3,000 cGy. He initially revised the directives to 1 treatment x ~1,000 cGy + 5 treatments x 350 cGy for a total dose of ~2,750 cGy. The next day, after discussing the case with a colleague, he revised the directives again, to a plan of 1 treatment x ~1,000 cGy + 4 treatments x 350 cGy for a total dose of ~2,400 cGy.

   For both patients, the area of the cervix had already been treated to 4,000 cGy by external beam treatments from a linear accelerator.

   We reviewed the records of all patients who had received similar treatments planned on this treatment planning system to ensure that we had not made a similar mistake in the past. Our review showed that we had not made such a mistake before.

4. **Why the event occurred:**

For this type of treatment, the positions of radiation sources and prescription points are entered into the treatment planning system using a digitizing tablet. For the positions to be entered properly, the correct magnification factor must be typed in at one point during data entry. If the magnification factor is not entered, the system assumes a magnification of 1.00. The magnification factor that we routinely use, which is determined from the source-axis distance and the source-film distance, is 1.45.

In these two cases the physicist inadvertently skipped the step of entering the proper magnification factor. The magnification factor does not appear on the printed treatment plan. Our method of QA consisted of the dosimetrist watching the physicist during data entry to ensure that no mistakes were made. The dosimetrist was on six weeks surgery leave during the first treatment of Patient A. The day of the first treatment of Patient B was her first day back, so instead we had our second medical physicist observe the data entry for those two treatment plans. He was not as fully familiar with the treatment planning system as the dosimetrist, however, and was less likely to catch the error.

5. **The effect, if any, on the individuals who received the administration:**

The prescribing physician does not expect a significant effect on the individual, either in terms of efficacy of treatment or in potential side effects.

6. **Actions taken to prevent recurrence:**

We have already put into place three actions to prevent recurrence.

a. If the data points are digitized correctly, the two prescription points will be approximately 4 cm apart. **We will measure the distance between those points and if there is significant variance from 4 cm, we will review the data entry to determine the cause of that variance.** In the seven treatments we have performed since we initiated that action, the distance has ranged from 3.988 cm to 4.15 cm. In the two treatment plans that contained errors, the distances were 5.75 cm and 5.86 cm, so this is clearly a strong indicator of error.

b. We developed a checklist that we will use during data entry. That checklist includes checking the magnification factors for the films used.

c. We developed a spreadsheet that lets us perform a completely independent calculation of the doses to the prescription points, based on the simplifying assumption that the sources act as point sources. **We will use this to estimate the doses to the prescription points, and if the estimated average dose to the prescription points is more than 10 % different from the computed average dose, we will review the plan for the source of the error.** In the seven treatments for which we have used this backup estimation spreadsheet, the variations have ranged from 0.8% to 2.7%

7. Notification of the individuals:

We hereby certify that we have notified both individuals.

The prescribing physician contacted the referring physician on April 19, 2006, within 24 hours of our discovery of the events. The same physician referred both patients.

The referring physician preferred that we wait until April 21, 2006, to notify the patients. This was the date of their next treatments. The referring physician did not want an immediate notification to alarm the individuals and cause them anxiety that might cause them to discontinue treatment. The referring physician believed that discontinuing treatment at that time would have been harmful.

The prescribing physician notified the individuals at the time of their next treatments on April 21, 2006. During that notification he informed them that a written description of the event would be available upon request.

Michael Tillman — 5/3/06
Chief Operating Officer — date

Michael A. Stewart, M.D. — 5/2/06
Radiation Oncologist — date

James W. Israel, M.S. — 5-2-06
Radiation Safety Officer and Chief Medical Physicist — date