RI - DNMS Licensee Event Report Disposition

Licensee: West Virginia University Hospital

Event Description: 2 Prescribed Dose

License No: 47-23066-02 Docket No: 3000233 MLER-RI: 2017-008

Event Date: 09/05/17 Report Date: 09/06/17 HQ Ops Event #: 52949

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	
X	Special Inspection	Inspector/Date	LTripp 9-18 to 19/2017
	Telephone Inquiry	Inspector/Date	PLambert 4-24 & 25/2018
	Preliminary Notification/Report		Daily Report
X	Information Entered in RI Log		Review at Next Inspection
	Report Referred To:		

3. REPORT EVALUATION

✓	Description of Event	✓	Corrective Actions
✓	Levels of RAM Involved	✓	Calculations Adequate
✓	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	N/A	Considered Need for AIT

Decision/Made By/Date: PL 4/23/18

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

✓	Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
N/A	Medical Consultant Used-Name of Consultant/Date of Report: not required per MC 1360
N/A	Medical Consultant Determined Event Directly Contributed to Fatality
No	Device Failure with Possible Adverse Generic Implications – isolated
No	HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

None - Special Inspection to be done

Non-Public, MD 3.4 non-public [redacted] Inspector Signature: [signature] Date: 4/26/18

✓ Public-SUNSI REVIEW COMPLETE Branch Chief Initials: [signature] Date: 5/29/18

Location of File: G:\REFERENCE\BLANK FORMS\LER FORM.DOCX

WestVirginiaUniversity.
RADIATION SAFETY DEPARTMENT

September 12, 2017

U.S. Nuclear Regulatory Commission
Penny Lanzisera, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

License No: 47-23066-02
Docket No: 03020233
Medical Event Reporting No: 52949

Dear Ms. Lanzisera,

On September 5, 2017 a patient was being administered the first fraction of a planned five fraction HDR Interstitial brachytherapy treatment, treating the cervix prescribed by Dr. John Vargo. The written directive prescribed five, 5Gy fractions for a total dose of 25Gy. During the first fraction, five separate interlocks were tripped at which time the manufacturer was contacted at 3:35pm. Based on discussions between the medical physics team and the manufacturer, the manufacturer determined the error was caused by fluid in the catheter, which may have contaminate the source and the afterloader unit. The manufacturer advised to suspend treatment and stop all use of the afterloader until it could be decontaminated and the source could be exchanged. The exchanged occurred on September 7, 2017.

It was determined that a split flexineedle attached to a transfer guidance tube that was then attached to the afterloader allowed fluid from the patient to enter the system.

At the time the treatment was stopped the patient received 0.32Gy of the planned 5Gy fraction, based on a 12.1 seconds treated of a planned 576.8 second treatment fraction. This resulted in a D90 = 0.32Gy to the HRCTV (treatment volume). A plan sum was created to account for dose received on 9/5/2017. The overall effect of 12.1 secs to the entire treatment accounted for an increase of 1.28% to the patient's treatment volume (D90 of HRCTV). This increase was considered by the physician in the creation of the final treatment plan on 9/7/2017.

Upon decontamination and source exchange, the patient received treatment per the written directive September 7-9, 2017. There were no adverse effects to the patient.

Based on 10CFR35.3045(a)(1) the fraction of the dose differed by more than 50 rem to organ or tissue, and 10CFR35.3045(a)(1)(iii) the fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more. . This is why this was reported to the NRC operation center as a medical event at 3:25pm on September 6, 2017.

Correction actions to prevent recurrence

- End caps will be placed at the time of OR to protect catheters from being exposed to liquid.

ROBERT C. BYRD HEALTH SCIENCES CENTER
WEST VIRGINIA UNIVERSITY
WVU HOSPITALS
JEFFERSON MEMORIAL HOSPITAL

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- All TGT's will be attached and measured at the time of sim
    - This will ensure proper connection and help the team decide which catheters can/won't be used
    - Any needles outside tolerance limit will not be utilized and removed from patient
    - Any liquid detected while measuring will automatically delete that catheter from use
- No treatment will be given if any team member is unsure of quality or safety.
- Movement towards metal needles and click-fit TGT's in the future will ensure fully closed system.
- New TGT's to be ordered, contaminated ones were disposed of.

In compliance with 10CFR35.3045(e) I certify that the patient and referring physician have been notified by Dr. Vargo.

If any other information is needed, I can be contacted at nrazmianfar@hsc.wvu.edu or 304-293-3413.

Sincerely,

Nasser Razmianfar
Director and Radiation Safety Officer