UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

May 25, 2018

Stephen Tancin, Vice President
Ancillary and Support Services
West Virginia University Hospital, Inc.
Medical Center, P.O. Box 9006
Morgantown, WV 26506-9006

SUBJECT: WEST VIRGINIA UNIVERSITY HOSPITAL, INC. - NRC INSPECTION NO. 03020233/2017001

Dear Mr. Tancin:

This letter refers to the inspection conducted on September 18-19, 2017, at your facility in Morgantown, West Virginia. The inspection was limited to a review of a medical event reported on September 6, 2017, involving the incomplete administration of a fractionated treatment with your high dose rate remote afterloader on September 5, 2017. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. In-office review continued thru April 24-25, 2018. An exit meeting was conducted with you and your staff on April 27, 2018, and the enclosed report summarizes our conclusions.

Within the scope of this inspection, no violations were identified.

Current NRC regulations and guidance are included on the NRC's Web Site at www.nrc.gov; select Nuclear Materials; Med, Ind, & Academic Uses; then Regulations, Guidance and Communications. The current Enforcement Policy is included on the NRC's Web Site at www.nrc.gov; select About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents; then Enforcement Policy (Under 'Related Information'). You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

If you have any questions regarding this matter, please contact Penny Lanzisera of my staff at 610-337-5169 or via electronic mail at penny.lanzisera@nrc.gov.

Thank you for your cooperation.

Sincerely,

Donna Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03020233
License No. 47-23066-02

Enclosure:
NRC Inspection Report No. 03020233/2017001

cc w/ enclosure:
Nasser Razmianfar, Ph.D., Radiation Safety Officer
State of West Virginia

If you have any questions regarding this matter, please contact Penny Lanzisera of my staff at 610-337-5169 or via electronic mail at penny.lanzisera@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Donna Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03020233
License No. 47-23066-02

Enclosure:
NRC Inspection Report No. 03020233/2017001

cc w/ enclosure:
Nasser Razmianfar, Ed.D., Radiation Safety Officer
State of West Virginia

DOCUMENT NAME: G:\WBL Documents\WBL Inspection Letter\L47-23066-02.2017001.docx
[ADAMS Accession No.]

SUNSI Review Complete: PLanzisera
After declaring this document "An Official Agency Record" it will be released to the Public.
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	RI:DNMS	n	RI:DNMS	N				
NAME	PLanzisera PL		DJanda DMJ					
DATE	5-21-18		5/25/18					

OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03020233/2017001
Docket No.	03020233
NMED Item No.	170427
License No.	47-23066-02
Licensee:	West Virginia University Hospital, Inc.
Location:	Morgantown, West Virginia
Inspection Dates:	September 18-19, 2017 April 27, 2018 (telephonic exit)
Date Followup Information Received:	April 24-25, 2018

Inspectors:

Lester Tripp — 5-21-18
for Health Physicist — date
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

Penny Lanzisera — 5-21-18
Senior Health Physicist — date
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

Approved By:

Donna Janda, Chief — 5/25/18
Medical and Licensing Assistance Branch — date
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

West Virginia University Hospital
NRC Inspection Report No. 03020233/2017001

An announced, special inspection was conducted on September 18-19, 2017, at West Virginia University Hospital (WVUH) in Morgantown, WV, to review the circumstances surrounding a medical event reported on September 6, 2017 (NMED Item Number 170427). In-office evaluation of the medical event, the applicator manufacturer's assessment of their device, and WVUH's corrective actions continued through April 25, 2018. The event involved the delivery of a fractionated high dose-rate remote afterloader (HDR) treatment on September 5, 2017, where an error occurred causing the HDR to shut down after delivering only 6.4 percent of the prescribed dose for the first fraction. A written report submitted by WVUH on September 12, 2017, concluded that a split flexineedle catheter connected to a transfer guide tube, attached to the HDR, allowed fluid to enter the HDR system; which caused the HDR to shut down. WVUH requested that Liberty Medical, Inc., the applicator manufacturer, examine their applicator for defects. The applicator manufacturer concluded on November 15, 2017, that "the needle tip was observed to be split" "consistent with a large force being applied to the inside of the needle tip," however, "the source of such force could not be determined." The applicator manufacturer also undertook engineering tests to attempt to duplicate the observed failure with no failure observed. No other split needles have been reported. Additional information provided by WVUH on April 24 and 25, 2018, was also reviewed.

Based on the results of this inspection, no violations were identified.

REPORT DETAILS

I. Event Description

a. Inspection Scope

An announced, special inspection was conducted on September 18-19, 2017, at WVUH in Morgantown, WV, to review the circumstances surrounding a medical event reported on September 6, 2017 (NMED Item Number 170427). The inspection was conducted in accordance with Inspection Procedure 87103 and Management Directive 8.10. An in-office review to evaluate the event, the applicator manufacturer's assessment of their device, and WVUH's corrective actions continued through April 25, 2018. The medical event was identified by WVUH during a routine patient treatment on September 5, 2017. The inspector conducted interviews with licensee personnel, toured the facility, and reviewed records applicable to the event.

b. Observations and Findings

HDR Program

License No. 47-23066-02 authorizes WVUH to provide HDR treatments at its facility in Morgantown, WV. The licensee began its HDR program several years ago and currently uses a Varian Medical Systems HDR. As a broad scope medical facility, WVUH approves their own authorized users and authorized medical physicists for performing these treatments.

Event Chronology, Reporting, On-Site Inspection, and Corrective/Preventative Actions

September 5, 2017 – A patient was scheduled to begin HDR treatments. A written directive was prepared documenting 5 fractions of 5 gray each for a total dose of 25 gray to the patient's cervix. During the first fraction, as reported by WVUH, five separate interlocks were tripped which stopped the treatment. At 3:35 p.m., the HDR manufacturer, Varian Medical Systems, was contacted and preliminary discussions indicated that fluid in the catheter may have contaminated the HDR unit. The HDR manufacturer suggested that treatments be suspended until maintenance on the unit could be completed. Maintenance was scheduled for September 7, 2017. The patient and their referring physician were notified of the event and treatment was rescheduled. No adverse effects to the patient were noted.

September 6, 2017 - WVUH reported the medical event to the NRC Operations Center and to Region I. In the report, WVUH indicated that the patient received 0.32 gray of the planned 5 gray fraction (i.e., 6.4%). WVUH also requested that the applicator manufacturer, Liberty Medical, Inc., examine the flexineedle catheter used in the treatment which was observed to be split.

September 7, 2017 – Varian Medical Systems arrived to decontaminate the unit from the introduced fluid, perform maintenance, and replace the source. The maintenance

included testing, verification, and calibration of all HDR system components. After cleaning and during source replacement, all tests normally conducted at each source exchange and annually were conducted, with a few tests from Varian Medical System's three year maintenance procedure also conducted. The manufacturer noted in their report that "All systems operations passed without any noted failures."

September 7-9, 2017 – The patient's treatment was re-planned on September 7, 2017, with consideration of the 0.32 gray already administered. The patient's treatment plan was approved by the authorized user and delivered as planned with no concerns noted.

September 12, 2017 – WVUH submitted its 15-day report in accordance with 10 CFR 35.3045. In the report, WVUH described the event, the suspected cause of the event, and the corrective actions to prevent recurrence. The corrective actions included: (i) placement of end caps in the operating room to protect the flexineedle catheters from being exposed to liquids; (ii) attachment of the flexineedle catheter to the guide tube during simulations to observe any failure of the catheter in connecting to the guide tube or in allowing liquid into the system prior to use; (iii) replacement of flexineedle catheters and guide tubes with metal needles and click-fit guide tubes to ensure a fully closed system; and (iv) replacement of current guide tubes with new guide tubes.

September 18-19, 2017 – NRC Region I conducted an on-site inspection to review the circumstances surrounding the reported medical event. The inspector conducted interviews with licensee personnel, toured the facility, and reviewed records applicable to the event and the completed treatment. The inspector also reviewed WVUH's procedures and documentation related to HDR use.

November 15, 2017 – The applicator manufacturer, Liberty Medical, Inc., completed its review of the flexineedle catheter and found that "the needle tip was observed to be split" "consistent with a large force being applied to the inside of the needle tip," however, "the source of such force could not be determined." The applicator manufacturer also: (i) confirmed that all flexineedle applicators are visually inspected and leak tested as part of the routine manufacturing process; (ii) performed a second visual inspection of all flexineedle catheters stored at their facility with no anomalies found; and (iii) undertook engineering tests to attempt to duplicate the observed failure with no failures occurring.

April 23-24, 2018 – NRC Region I contacted WVUH with additional questions which included: (i) did planned treatment depth match delivered treatment depth; (ii) are flexineedle applicators supplied at all the same length; (iii) in the follow-up treatment of the patients, were five fractions administered; (iv) are flexineedle catheters visually inspected prior to implanting ; (v) did WVUH attempt to reproduce the failure similar to the manufacturer; and (vi) when the dummy source was sent to channel 20 (the channel where the failed flexineedle catheter was located), were any errors observed?

April 24-25, 2018 – WVUH provided the following responses to the questions posed: (i) the dummy source was sent into the central tandem in Channel 1 and then to all other channels connected to flexineedle catheters, and the error was observed when the active source went into Channel 1 which, therefore never made it into the flexineedle applicators; (ii) the flexineedle catheters are all the same length +/- 2 millimeters; (iii) a

new plan was created with new needles inserted also using five fractions and accounting for the 0.32 gray already delivered; (iv) WVUH's authorized user visually inspects each flexineedle applicator prior to implanting them, with no concerns noted; (v) following the event, WVUH attempted to split a test needle by pushing very hard into the needle, but could not recreate a failure; and (vi) the dummy source traveled into and out of channel 20 with no errors produced. WVUH theorized that the authorized user may have encountered tough tissue when inserting the flexineedle catheter, that was later attached to channel 20 of the HDR, and when pushing hard on the catheter, that may have had a weak tip that was not visually observed, the tip split. The split tip then allowed fluid into the catheter that was picked up by the dummy source and transferred into the HDR unit, which caused an error at the next wire movement. The inspector reviewed the licensee's corrective actions against this theory and found the corrective actions appropriate for this type of event.

April 27, 2018 – A final exit meeting was conducted via telephone with WVUH's Vice President of Ancillary and Support Services, Radiation Safety Officer, and Radiation Safety staff. During the exit, the inspector summarized the event, the event reporting, the manufacturer's review, and WVUH's corrective and preventative actions.

c. Conclusions

WVUH reported the medical event as required by 10 CFR 35.3045 and took appropriate corrective and preventative actions. WVUH also notified the involved patient and their referring physician of the event, observed no adverse effects to the patient, and completed the patient's treatment with no concerns noted. Based on the inspector's observations, no violations of NRC requirements were identified.

II. Exit Meeting

A preliminary exit meeting was conducted on September 19, 2017, to discuss the scope of the inspection and the inspector's initial observations. On April 27, 2018, an exit meeting was held by telephone with Mr. Stephen Tancin, Vice President, Ancillary and Support Services, and other members of WVUH's staff, to discuss the results of this inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

+* Stephen Tancin, Vice President, Ancillary and Support Services
+* Nasser Razmianfar, Ed.D., Radiation Safety Officer
+* Stephen Root, M.S., Radiation Safety staff
Various Authorized Users and Authorized Medical Physicists

* Present at preliminary exit meeting on September 19, 2017
+ Participated in telephonic exit meeting conducted on April 27, 2018