

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03020233/2022001
Docket No. 03020233
License No. 47-23066-02
EA No. EA-22-080
Licensee: West Virginia University Hospitals, Inc.
Address: P.O. Box 9006
Morgantown, WV 26506-9006
Inspection Dates: July 22, 2022
Exit Meeting September 30, 2022

Inspector: _____
Robin L. Elliott
Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
_____ date

Approved By: _____
Anne DeFrancisco
Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
_____ date

EXECUTIVE SUMMARY

West Virginia University Hospitals, Inc.
NRC Inspection Report No. 03020233/2022001

On July 22, 2022, the NRC initiated an announced reactive inspection to review the organization and scope of activities performed under the West Virginia University Hospitals, Inc. (WVUH) NRC License No. 47-23066-02 after they reported the loss of one I-125 brachytherapy seed used in a routine radioactive seed localization (RSL) procedure on June 16, 2022 (EN #55994). WVUH is a large medical broad scope licensee operating five licensed facilities in the state. They are authorized for a wide range of materials including: 10 CFR 35.100, 200, 300, 400, 600 and 1000 activities. The event occurred when, on June 16, 2022, two seeds were implanted into the right breast of a patient, which was not typical, and one seed was implanted into the left breast of the same patient. The seeds were removed from the patient in the operating room, sent to the breast center for mammography, which confirmed the removal of all three seeds, then sent to Gross Pathology, without the containers being labelled with the number of seeds contained. The information about the seeds was present on the requisition form. At Gross Pathology, the lab technician presented the specimens to the resident to be processed. The lab technician prepared the specimens providing only one vial, rather than two, for the right breast specimen to contain the removed seeds. The resident removed only one seed from the right breast specimen, verified the one seed in the vial, and did not find another seed. The resident did not survey the work area but only surveyed the bag that contained the specimen at the completion of work. The loss of the seed was not discovered until Radiation Safety staff collected seeds from the Gross Pathology lab and performed an accounting on June 22, 2022.

Three violations of NRC requirements were identified involving the failures to meet: 1) 10 CFR 20.1501 (a)(2)(ii) and 10 CFR 20.2001(a) which requires licensees to perform surveys to evaluate concentrations or quantities of residual radioactivity to verify disposal of licensed material only by authorized methods; 2) the requirements of licensee-developed procedures which require the container holding the specimen to be labelled with the number of seeds contained; and 3) the requirements of licensee training programs which require annual training for staff involved in the RSL program.

The licensee took immediate and comprehensive corrective actions which included: 1) all areas (Breast Care Center, Operating Room staff, Pathology staff, and Radiation Safety Staff) involved in the RSL program received in-person radiation safety training with particular emphasis on the causes for the event, appropriate seed tracking documentation, and notification requirements; 2) establishment of a survey requirement for Pathology of all work stations and trash after they have grossed a specimen containing a radioactive seed; 3) Pathology and Radiation Safety were provided access to the seed tracking flow sheet in Epic to document the movement of the seeds from cradle-to-grave; 4) listing the total number of seeds excised from the patient in the specimen on the pathology requisition which will accompany the specimen to the Breast Center for mammography and then to Pathology for seed removal; 5) the seed tracking flowsheet was edited to add document verification to support that the Breast Care Center confirms that the number of seeds in the mammography image with the total number of seeds indicated on the pathology requisition.

REPORT DETAILS

1. **Organization and Scope of the Program**

a. Inspection Scope

The inspector reviewed the organization and scope of Radioactive Seed Localization (RSL) activities performed under WVU's NRC License No. 47-23066-02. Information was gathered through interviews with licensee staff, including the Radiation Safety Officer (RSO), Radiation Safety Staff, Radiation Safety Committee (RSC) representatives, Pathology staff, tours of use areas associated with RSL activities and through a review of selected documents related to RSL and the reported event.

b. Observations and Findings

West Virginia University Hospitals, Inc. (WVUH) is a medical broad scope licensee authorized for medical use under 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 [high dose rate afterloader (HDR) and gamma stereotactic radiosurgery (GSR)], 35.1000 [Y-90 microsphere therapies and radioactive seed localization (RSL)], and medical research. Locations of use are Ruby Memorial Hospital, Mary Babb Randolph Cancer Center, Health Sciences Center, Jefferson Memorial Hospital, and Fairmont Regional Cancer Center.

The WVUH's radiation safety program is managed by the RSC supported by the RSO and Radiation Safety Department. The RSL program was presented and approved by the RSC.

2. **Review of Licensed Activities**

a. Inspection Scope

The inspector performed an onsite announced reactive inspection utilizing NRC Inspection Procedure 87134, "Medical Broad Scope Programs." Information was gathered through interviews with cognizant personnel and a review of records.

b. Direct Observations, Interviews, and Records Review

The inspector reviewed several documents relative to the program: Procedures for Use of I-125 Radioactive Seeds for Localization of Non-palpable Breast Lesions, RSC approvals for the Authorized Users (AU) designated to perform RSL procedures, I-125 Seed Pick-up Procedure, RSL Program Radiation Safety training records, Training Power Point presentations, Radiation Safety: Reported Incident Log Sheet for the lost seed event, mammography images of both specimens taken from the patient's breast lesions, post excision mammography dictation, seed tracking documentation, communications between Radiation Safety staff and the resident that grossed the specimens, the written directive for the procedure, the AU's implantation dictation,

Pathology's dictation, the surgeon's dictation, the seed tracking sheet, Radioactive Log Book located in gross pathology, and the corrective action plan.

The inspector interviewed members of the: Pathology Program including the resident who removed the seeds from the specimens, Radiation Safety staff, Clinical Labs, and a member of the RSC. The inspector toured the Gross Pathology laboratory and observed: the workstations, location of sinks in relation to the workstation, the location of the biohazardous waste receptacles relative to the workstation, discussed with the staff how they prepare the specimens for the pathology resident to remove the seeds, and how the seeds are stored once removed from the specimen as well as the logbook for recording the seeds in storage. The inspector also walked the path the biohazardous waste took from the Gross Pathology lab to the loading dock and observed how the waste was processed prior to removal. Lastly, the inspector observed an RSC meeting at which the incident was briefed out.

c. Conclusions

Three violations of NRC requirements were identified and determined to be categorized as Severity Level IV violations.

3. Exit Meeting

An exit meeting was held with Nathan Burt and Stephen Root on September 30, 2022, where WVUH representatives were informed that the violations would be cited at Severity Level IV and told that their corrective actions were sufficient such that no further response was required.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

+Patrick Bacaj (Associate Professor of Pathology)
+Albert Berrebi (Assistant Vice President for Research) (RSC member)
+#Kristen Daft (Radiation Safety Specialist)
+Jared Drvar (Anatomic Pathology Manager)
+Melina Flanagan (Pathology Residency Director, Director of Anatomic Pathology)
+Traci Hinkle (Director Clinical Labs/Pathology)
+Rehab Mohamed (Pathology Resident)
+Stephanie Owens (Medical Tech Specialist, Clinical Labs)
+#^Stephen Root (Radiation Safety Manager)
^Nathan Burt (Vice President of Operations)

Individual(s) present at virtual entrance meeting
+ Individual(s) present for onsite inspection debrief on July 22, 2022
^ Individual(s) present for virtual exit meeting on September 30, 2022

INSPECTION PROCEDURES USED

IP 87134, Medical Broad Scope Programs

LIST OF ACRONYMS USED

AU: Authorized User
CFR: Code of Federal Regulations
EN: Event Notice
GSR: Gamma Stereotactic Radiosurgery
HDR: High Dose Rate Remote After Loader
NRC: Nuclear Regulatory Commission
RSC: Radiation Safety Committee
RSL: Radioactive Seed Localization
RSO: Radiation Safety Officer
WVU: West Virginia University Hospitals, Inc.