



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD – SUITE 102  
KING OF PRUSSIA, PA 19406-1415

October 28, 2022

EA-22-080

Nathan Burt  
Vice President of Operations  
West Virginia University Hospitals, Inc.  
P.O. Box 9006  
Morgantown, West Virginia 26506-9006

**SUBJECT: WEST VIRGINIA UNIVERSITY HOSPITALS, INC. - NRC INSPECTION NO. 03020233/2022001 AND NOTICE OF VIOLATION**

Dear Mr. Burt:

This letter refers to the inspection conducted on July 22, 2022, at West Virginia University Hospital, Inc. (WVUH) facilities at your Morgantown, West Virginia location. 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. On July 22, 2022, at the conclusion of the onsite portion of the inspection, the inspector discussed the preliminary inspection findings with Albert Berrebi, Assistant Vice President for Research and Radiation Safety Committee member, Stephen Root, Radiation Safety Manager and other WVUH staff. A telephonic exit meeting was conducted with you and Stephen Root on September 30, 2022.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. These violations are being cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report No. 03020233/2022001. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide

Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

Should you have any questions regarding this letter, the inspection report, or the enclosed Notice, please contact Robin L. Elliott of my staff at 610-337-5076 or via email at [Robin.Elliott@nrc.gov](mailto:Robin.Elliott@nrc.gov).

Thank you for your cooperation.

Sincerely,

Anne DeFrancisco, Chief  
Medical and Licensing Assistance Branch  
Division of Radiological Safety and Security  
Region I

Docket No. 030-20233  
License No. 47-23066-02

Enclosure:  
Notice of Violation  
Inspection Report

cc w/ enclosure

Nasser Razmianfar, Radiation Safety Officer  
Stephen Root, Associate Radiation Safety Officer  
State of West Virginia

WEST VIRGINIA UNIVERSITY HOSPITALS, INC - NRC INSPECTION NO. 03020233/2022001 AND NOTICE OF VIOLATION DATED OCTOBER 28, 2022

DISTRIBUTION:

- B. Welling, DRSS, RI
- T. Bloomer, DRSS, RI
- A. DeFrancisco, DRSS, RI
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## NOTICE OF VIOLATION

West Virginia University Hospitals, Inc. (WVUH)  
Morgantown, WV

Docket No. 030-20233  
License No. 47-23066-02  
EA-22-080

During an NRC inspection conducted on July 22, 2022, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1501 (a) requires that each licensee shall make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20 and are reasonable under the circumstances to evaluate concentrations or quantities of residual radioactivity.

10 CFR 20.2001(a) requires, in part, that the licensee shall dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits in 10 CFR Part 20.

Contrary to the above, on or about June 16, 2022, WVUH did not make or cause to be made surveys of areas that were necessary for the licensee to comply with the regulations in 10 CFR Part 20 and were reasonable under the circumstances to evaluate concentrations or quantities of residual radioactivity. Specifically, a survey of the gross pathology area was not performed, which would have detected the presence of a 0.268 mCi I-125 brachytherapy seed that was present in a tissue specimen. As a result, the licensee failed to dispose of the licensed material only by transfer to an authorized recipient, decay in storage, or release in effluents within the limits in 10 CFR Part 20 when the licensee inadvertently improperly disposed of the brachytherapy seed, likely as biohazardous waste.

This is a Severity Level IV violation (Enforcement Policy Section 2.3.4).

- B. License Condition 20 of NRC license no. 47-23066-02, requires in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter application dated November 15, 2011.

Procedures for Use of I-125 Radioactive Seeds for Localization of Non-palpable Breast Lesions dated October 24, 2013: Section C, item 6. states, "The specimen must be labeled as radioactive and the total number of radioactive seeds contained within the specimen should be indicated on the label."

Contrary to the above, on June 16, 2022, a specimen was not labeled with the total number of radioactive seeds contained within the specimen on the label. Specifically, the container holding the right breast specimen was not labeled as containing two seeds.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d).

- C. License Condition 20 of NRC license no. 47-23066-02, requires in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter application dated November 15, 2011.

The model training program in NUREG 1556 Vol.9 Rev. 2 states, "Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used."

Contrary to the above, in 2021, WVU did not provide annual refresher training to personnel with duties involving radioactive materials. Specifically, a gross pathology resident received refresher training in 2020 and did not receive additional training until July 20, 2022.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket in NRC Inspection Report No. 03020233/2022001. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, (EA-22-080)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room (PDR) or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 28th day of October, 2022