

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED

West Virginia University Hospitals, Inc.
Medical Center Drive
Morgantown, WV 26506

2. NRC/REGIONAL OFFICE

Region 1
2100 Renaissance Blvd
Suite 100
King of Prussia, PA 19406-2713

REPORT NUMBER(S) 2020001

3. DOCKET NUMBER(S)

030-20233

4. LICENSE NUMBER(S)

47-23066-02

5. DATE(S) OF INSPECTION

10/27/2020 - 10/28/2020, in office
review through 12/7/2020

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

1 Non-cited violation(s) were discussed involving the following requirement(s):

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on August 29, 2019, the licensee did not control or maintain constant surveillance of an aggregate quantity less than 1000 times 10 CFR 20 Appendix C of Ba-133, Co-57, Cs-137, Eu-152, In-111, Tc-99m and Tl-201 located in the nuclear cardiology hot lab, which is a controlled area. Specifically, on August 29, 2019, a vendor was allowed access to and propped open the nuclear cardiology hot lab door for an undetermined amount of time. The licensee identified this violation and implemented corrective actions which included changing their vendor training policy and providing re-instruction to applicable staff on the control of licensed material.

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with the NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11. (Violations and Corrective Actions)

A. 10 CFR 35.633(a) states, in part, that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit before medical use following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly.

Contrary to the above, on July 8, 2019, and July 11, 2019, the licensee was authorized to use a remote afterloader unit for medical use and did not perform full calibration measurements following repair of the unit that included removal of the source and major repair of the components associated with the source exposure assembly. Specifically, on July 8 and 11, 2019, the source was removed from the unit and major repairs were conducted on the unit that involved the source exposure assembly

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

Corrective actions included revising the remote afterloader manual to require the authorized medical physicist to determine if the source was removed or if major repairs were made to the source exposure assembly during service and if so, recalibrate the unit. Additionally, the licensee's procedures require the radiation oncology department to contact the radiation safety department when non-routine maintenance and re-calibrations are performed so that the radiation safety department can provide oversight of the work.

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B.10 CFR 35.60(b) states, in part, a licensee shall calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions.


Contrary to the above, on November 5, 2019, the licensee did not calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, the licensee failed to perform a geometric independence test for a 30 milliliter vial, used for Lu-177 and Y-90 therapy treatments, upon reinstallation of the dose calibrator on November 5, 2019, as required by the manufacturer's instructions. Furthermore, as of October 27, 2020, the licensee failed to establish the appropriate calibration setting number for Lu-177 and Y-90 measured in 30 milliliter glass vials, as required by the manufacturer's instructions.

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

Corrective actions included performing the necessary geometric independence testing and establishing the appropriate calibration setting numbers for Lu-177, Y-90 SIR-Spheres, and Y-90 TheraSpheres. Additionally, the licensee created a procedure and checklist to ensure that all required tests are performed upon reinstallation, repair, or relocation of the dose calibrators.

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE	Nathan Burt, VP Operations		12/21/2020
NRC INSPECTOR	Penny Lanzisera	Penny A. Lanzisera	Digitally signed by Penny A. Lanzisera Date: 2020.12.21 10:10:38 -05'00'
BRANCH CHIEF	Donna M. Janda		