NRC FORM 591M PART 1
(04-2022)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED	2. NRC/REGIONAL OFFICE
MedStar Washington Hospital Center 110 Irving Street, N.W., Washington, DC 20010-2975 **REPORT NUMBER(s) 2024001**	Region 1 475 Allendale Rd Suite 102 King of Prussia, PA 19406

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01325	08-03604-03	03/04/2024 - 07/29/2024

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 violations(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.

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

☑ 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)

10 CFR 20.1501(a), states in part, 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 20 and are reasonable under the circumstances to evaluate the concentrations or quantities of residual radioactivity and the potential radiological hazards of the residual radioactivity detected.

Contrary to the above, on numerous occasions between January 4, 2022, and March 4, 2024, the licensee did not make or cause to be made proper routine contamination surveys to evaluate the concentration or quantities of residual radioactivity and the potential radiological hazards of the residual radioactivity detected. Specifically, routine contamination surveys were not adequately performed due to the failure to use efficiency factors associated with the instrumentation. Contamination surveys need to take into account background counts, detector efficiencies, and geometric factors. Without these factors applied the decontamination survey measurements may not accurately measure the activity of any potential contamination that may be present.

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

License Condition 21 of USNRC license No. 08-03604-03, requires, in part, that the licensee shall conduct its program in accordance with the statements, representation, and procedures contained in the application dated November 1, 2016.

Radiation Safety Procedure During Lu-177 Dota-tate (Lutathera) Treatment dated July 2018, Section 3. (ii) states, "A calibrated GM detector shall be used for monitoring of contamination on equipment and personnel."

Contrary to the above, on February 28, 2024, the licensee conducted a Lu-177 Dota-tate treatment and failed to conduct contamination surveys with a GM detector resulting in a failure to identify a contaminated infusion pump which was moved to an area that was not designated for use of licensed material.

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

For corrective actions, the licensee has provided the radiation safety team with a refresher training on the use of proper survey meters and the implementation of all procedures.

NRC FORM 591M PART 1
(04-2022)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED	2. NRC/REGIONAL OFFICE
MedStar Washington Hospital Center 110 Irving Street, N.W. Room BA94 Washington, DC 20010-2975 **REPORT NUMBER(s) 2024001**	Region 1 475 Allendale Rd Suite 102 King of Prussia, PA 19406

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01325	08-03604-03	03/04/2024 - 07/29/2024

10 CFR 35.633(a)(2)(i) states, in part, that a licensee authorized to use a remote after loader unit for medical use shall perform full calibration measurements on each unit before medical use following replacement of the source. 10 CFR 35.633(b)(7) states, in part, that to satisfy the requirements of paragraph (a) of this section full calibration measurements must include determination of function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

Contrary to the above, between January 4, 2022, and March 4, 2024, the licensee was authorized to use a remote after loader unit for medical use and did not perform full calibration measurements that included the function of the source transfer tubes, applicators, and transfer tube-applicator interfaces. Specifically, the licensee performed this evaluation for the cylinder applicators but not the tandem and ring applicators.

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

For corrective action, the licensee has updated their procedures to perform full calibrations on cylinders and tandem and rings applicators quarterly.

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	Mohammed Aljallad, Ph.D., RSO	Mohammed Aljallad	8/5/24
NRC INSPECTOR	Robin Elliott	ROBIN ELLIOTT Digitally signed by ROBIN ELLIOTT Date: 2024.08.01 15:58:25 -04'00'	
BRANCH CHIEF	Anne DeFrancisco		8/14/24