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

July 27, 2023

EN56309

Reggie L. Pearson,
Vice President Operations
MedStar Georgetown Medical Center, Inc.
d/b/a MedStar Georgetown University Hospital
1 Main Hospital, 3800 Reservoir Road N.W.
Washington, D.C. 20007

SUBJECT: NRC INSPECTION REPORT 030-35409/2023-001

Dear Reggie Pearson:

This letter refers to the announced reactive inspection conducted from May 15 through June 27, 2023. The inspection, conducted remotely, was an examination of a reported medical event which occurred on January 11, 2023, involving a yttrium-90 microsphere administration, which resulted in an underdose to the patient. This event was reported to the NRC within one business day, as required under the reporting criteria in 10 CFR Part 35. The NRC determined through internal review that additional follow-up was appropriate, necessary, and consistent with Management Directive 8.10 (available at: https://www.nrc.gov/reading-rm/doc-collections/management-directives/volumes/vol-8.html). Within the scope of the inspection, the inspection reviewed your licensed activities conducted under your license as they relate to this medical event, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the conditions of your license. Specifically, the inspection consisted of interviews with personnel and a selected examination of procedures and representative records from the licensee and source manufacturer. A final exit briefing was conducted telephonically with Matthew Williams, Radiation Safety Officer and Director of Radiation Safety and Diagnostic Physics, on June 27, 2023.

Based on the results of this inspection, the NRC has determined that no violations of NRC requirements were identified; therefore, no response to this letter is required. The details of our review of the yttrium-90 administration and the facts and circumstances related to the associated medical event are contained in the enclosure to this letter.

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, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agencywide Document Access and Management System (ADAMS), accessible from the NRC website 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.

If you have any questions related to this matter, please contact me at (610) 337-5078 or Anne.DeFrancisco@nrc.gov.

Sincerely,

Christopher G. Cahill Digitally signed by Christopher G. Cahill
Date: 2023.07.27 15:41:30 -04'00'

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

Docket No. 030-35409
License No. 08-30577-01

Enclosure:
NRC Inspection Report 030-35409/2023-001

cc w/ enclosure:
Matthew H. Williams, Radiation Safety Officer

NRC INSPECTION REPORT 030-35409/2023-001 DATED JULY 27, 2023.

Distribution:
A. DeFrancisco, DRSS
J. vonEhr, DRSS
P. Krohn, DRSS
J. Quichocho, DRSS

ADAMS ACCESSION NUMBER:

☒SUNSI Review: By: JEV	ADAMS: ☒ Yes ☐ No	☐ Non-Publicly Available ☒ Publicly Available	☒ Non-Sensitive ☐ Sensitive	Keyword: N/A

OFFICE	RI:DRSS	RI:DRSS				
NAME	JvonEhr	ADeFrancisco				
SIGNATURE	JEV	AED				
DATE	06/27/2023	7/10/23				

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Docket:	030-35409
License:	08-30577-01
Report:	2023-001
Event No.:	EN56309
Licensee:	MedStar Georgetown Medical Center, Inc. d/b/a MedStar Georgetown University Hospital
Locations Inspected:	N/A Remote Inspection
Inspection Dates:	May 15 – June 27, 2023

Inspectors: *Jason vonEhr* 07/27/2023
Jason vonEhr, Senior Health Physicist Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Approved By: *Chris Cahill /for* 07/27/2023
Anne DeFrancisco, Chief Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Attachment: Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

MedStar Georgetown Medical Center, Inc.
d/b/a MedStar Georgetown University Hospital
NRC Inspection Report 030-35409/2023-001

An announced reactive inspection was performed of MedStar Georgetown Medical Center, Inc. on May 15 through June 27, 2023. The inspection was an examination of a reported medical event which occurred on January 11, 2023, involving a yttrium-90 microsphere administration which resulted in an underdose to the patient. Within this scope, the inspection reviewed the licensed activities conducted under the license as they relate to this medical event, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules, regulations, and with the conditions of the NRC license.

Program Overview

MedStar Georgetown Medical Center, Inc. is authorized by the NRC License No. 08-30577-01 to use, in part, yttrium-90 microspheres for medical diagnosis, therapy, and research in humans. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in Washington, D.C.

Inspection Findings

Based on the results of this inspection, the NRC has determined that no violations of NRC requirements were identified.

REPORT DETAILS

1. Program Overview (Inspection Procedure 87103)

1.1. Program Scope

MedStar Georgetown Medical Center, Inc., doing-business-as MedStar Georgetown University Hospital ("MedStar") was authorized by the U.S. Nuclear Regulatory Commission Materials (NRC) License No. 08-30577-01, a medical institution broad scope license. This license authorized, in part, yttrium-90 microspheres for medical diagnosis, therapy, and research in humans. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in Washington, D.C.

1.2. Inspection Scope

The inspection was an examination of a reported medical event which occurred on January 11, 2023, involving a yttrium-90 microsphere administration which resulted in an underdose to the patient. Within this scope, the inspection reviewed MedStar's licensed activities conducted under the NRC license as they relate to this medical event, to confirm compliance with the NRC rules, regulations, and with the conditions of the NRC license. Specifically, the inspection consisted of interviews with personnel and a selected examination of procedures and representative records from the licensee and microsphere manufacturer, Boston Scientific, Inc.

2. Reactive Inspection of Medical Event

2.1. Timeline of the Medical Event

The licensee Authorized User (AU) signed and dated a written directive on January 11, 2023. The written directive was consistent with Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40(b)(2) and prescribed a 185 cubic centimeter volume of patient's liver tissue (Liver Segments 5 and 8) to receive a target dose of 330 Gray. The licensee's treatment plan called for 1.367 gigabecquerel (GBq) (37 millicuries) of yttrium-90 microspheres to achieve this exposure goal for the target tissue volume.

The licensee performed receipt quality assurance tests and measurements at approximately 12:57 pm on January 11, 2023. The received yttrium-90 microsphere vial was measured to be 1.339 GBq, or approximately two percent less than the treatment called for (within acceptable manufacturer margins). The administration commenced at 1:55 pm that same day with no observed issues. The AU recalled to the inspector that the microcatheter was flushed with saline with a volume and rate-of-flow as recommended by the manufacturer's instructions, and that no kinks, obstructions, or unexpected radiation measurements were noted.

In the post-treatment measurement, MedStar personnel determined that only 66 percent of the anticipated activity was delivered to the target tissue (approximately 0.903 GBq, or 24.4 millicuries). The description of the post-treatment measurement of the vial and associated equipment was consistent with manufacturer recommendations and standard industry practices. No contamination was identified in or around the room or associated equipment, and the remaining radioactive material (estimated 0.46 GBq, or 12.4 millicuries) was determined to remain within the delivery apparatus. This resulted in

an estimated 217.9 Gray to the patients' target tissue volume, in contrast to the intended 330 Gray.

2.2. Reportability and Timeliness

Based on the details described above, the patient experienced a medical underdose sufficient to meet the criteria in 10 CFR 35.3045(a)(1)(i)(A): the administration did not result from patient intervention; involved the administration of byproduct material other than that associated with permanent implant brachytherapy; had a dose that differed from the prescribed dose by at least 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue; and differed from the prescribed dose by 20 percent or more. In the case of the January 11, 2023, administration, the treatment was not permanent implant brachytherapy; involved a dose that differed by 112.1 Gray (approximately 11,210 rem) to an organ (the liver); and differed from the prescribed dose by 34 percent. As a result of all the above, the administration was determined to be a medical event and reportable to the NRC under the above-quoted regulation.

As required by 10 CFR 35.3045(c), the licensee was required to notify, by telephone, the NRC Operations center no later than the next calendar day after discovery of the medical event. 10 CFR 35.3045(d) in turn required the licensee to provide a written report to the NRC within 15 days following the discovery of the medical event.

The NRC Operations Center documented MedStar's telephone notification on January 12, 2023, at 08:26 Eastern Standard Time, thus meeting the requirement for timely notification as described in 10 CFR 35.3045(c). The licensee further provided a written report to the NRC (Document Access and Management System (ADAMS) Accession No. ML23020A102), dated January 19, 2023, where the licensee provided further information regarding the medical event. The content of this report was reviewed and found to adequately address the associated requirements in 10 CFR 35.3045(d)(1)(i) through (d)(1)(vii). The licensee was deemed timely in the provision of this report to the NRC.

The licensee clarified to the inspector over the phone the written report's typo regarding: (1) the plurality of "patients" quoted in the licensee's report in the Certification of notification to the patient/caregiver (i.e. there was only one patient); and (2) the "electron" dosimeter versus "electronic" dosimeter quoted in the report in the section titled "Why the Event Occurred."

2.3. Licensee and Manufacturer Follow-Up to Medical Event

The licensee performed SPECT/CT (single-photon emission computed tomography / computed tomography) imaging on the patient and imaged the equipment to ascertain the location and distribution of the radioactive material. The licensee determined that the treatment achieved the intended medical outcome and no further follow-up by the patient would be required. The licensee's equipment image (seen below in Figure 1) appeared to show an occultation or blockage, possibly the result of a 'kink' within the delivery tubing and thus likely inhibited the flow of these microspheres into the patient and

resulting in a build-up of yttrium-90 microspheres.

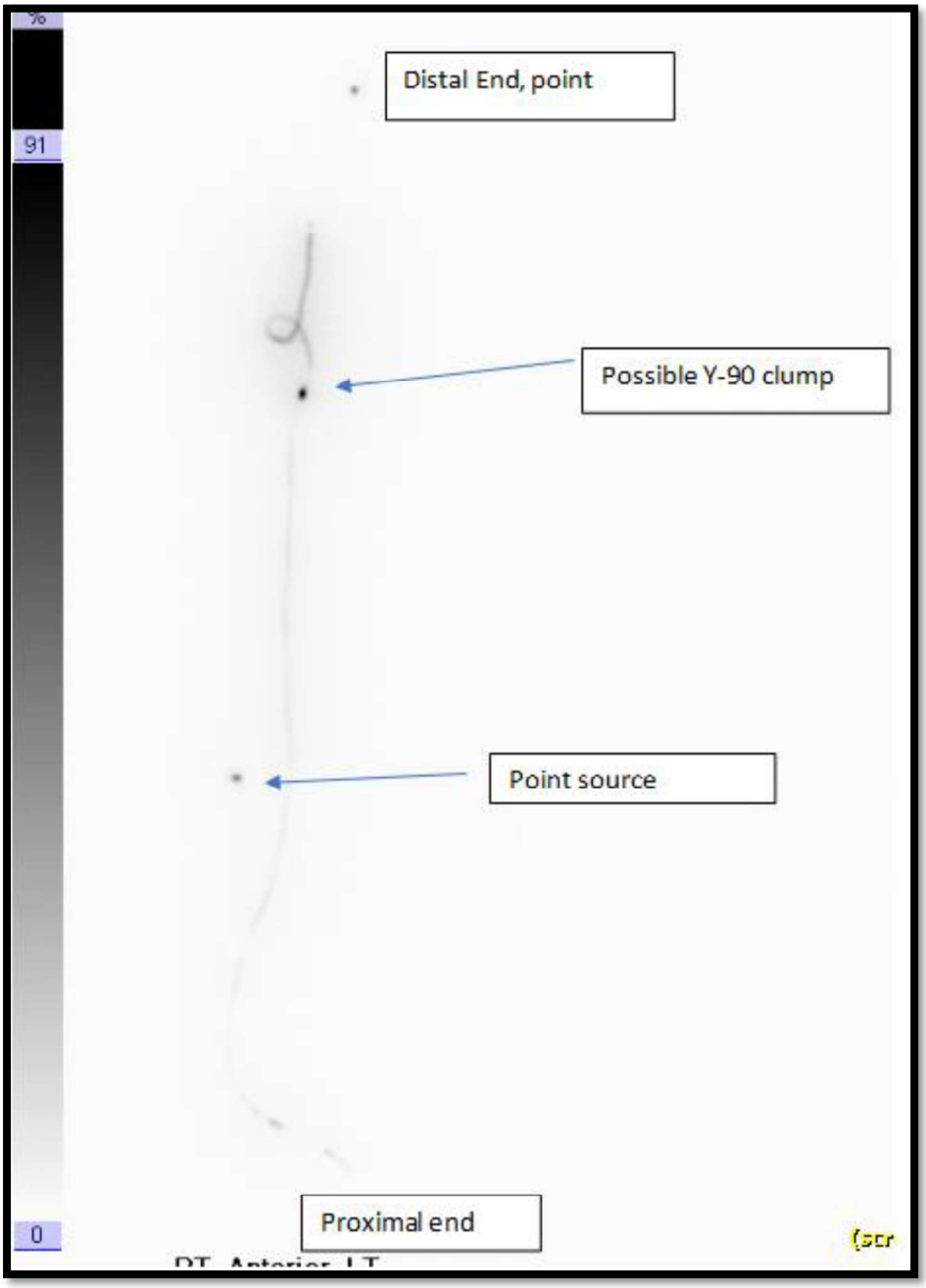

Figure 1 – MedStar imaging of the equipment showing an occultation or blockage in the delivery tubing, leading to a build-up of yttrium-90 microspheres (shown as black and dark-gray in the image)

MedStar described in their January 19, 2023, report that it will institute the use of a second electronic dosimeter nearer the patient in an attempt to identify whether the radioactive material has become blocked or a build-up of radioactive material has occurred between the delivery apparatus and the patient. The licensee's prior standard practice included the use of an electronic dosimeter near the delivery system to be able to infer the successful delivery of the yttrium-90 microspheres from the vial. However,

the licensee correctly noted that this single dosimeter would not be able to identify radioactive material between the vial and the patient, and therefore gave them a false indication of whether or not the delivery of the microspheres on January 11, 2023, was successful.

The licensee took further steps to coordinate with the manufacturer, Boston Scientific, to perform an analysis of the delivery apparatus. The licensee allowed the residual yttrium-90 microspheres to decay to sufficiently low radiation levels to allow shipment of the apparatus to Boston Scientific. Boston Scientific provided a report dated May 22, 2023 (ADAMS Accession No. ML23159A037) with their findings and observations. The report describes the analysis by the Boston Scientific Quality Assurance Laboratory, which found, in brief, a kink in the outlet tubing at the pinch clamp. Boston Scientific noted that this observation is not necessarily consistent with the actual condition of the product prior to or during the administration as a result of changes that may result from physically shipping the product. The conclusion by Boston Scientific was that the low delivery of microspheres appeared to be the result of insufficient flow but acknowledged that this may be the result of tube occlusion, kinked microcatheter, inadequate saline flush, or "torturous" patient anatomy.

In summary, the licensee's conclusion that an obstruction or kink in the delivery tubing was not ruled out or contradicted by the manufacturer's observations and findings.

2.4. NRC Observations and Findings

No violations were identified during the NRC's review, either with the licensee's treatment planning, execution, or reporting to the NRC following discovery of the medical event. In addition, the inspection did not identify any program weaknesses nor deviations from standard industry practices or manufacturer recommendations that may have contributed to the root cause of the January 11, 2023, medical event.

With regards to the licensee's compensatory measure of adding a second dosimeter: while the second electronic dosimeter will not necessarily prevent a future medical event from occurring (as it does not prevent or directly address deficiencies in the delivery system), the second dosimeter will provide the licensee an important indication of whether additional compensatory measures are warranted if radioactive material is detected between the microspheres' vial and the patient. These measures may include actions such as additional saline flushes or adjustments in the delivery tubing to try to relieve an obstruction, which in turn may allow a higher fraction of the intended radioactive material to be successfully delivered to the patient and thus reduce the likelihood of a future medical event.

2.5. Conclusions

As a result of the NRC's review, no items of concern or noncompliances were identified.

3. Exit Meeting Summary

The NRC conducted a final exit briefing via teleconference with Matthew Williams, Radiation Safety Officer and Director of Radiation Safety and Diagnostic Physics, on June 27, 2023. The licensee again acknowledged the findings presented and did not dispute any of the facts presented.

SUPPLEMENTAL INSPECTION INFORMATION

LIST OF PERSONS CONTACTED

Matthew Williams, Radiation Safety Officer, Director of Radiation Safety and Diagnostic Physics
Fil Banovac, M.D., Authorized User and Prescribing Physician

INSPECTION PROCEDURES USED

87103, Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

None

Closed

None

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
CFR	*Code of Federal Regulations*
d/b/a	Doing-Business-As
GBq	Gigabecquerel
MedStar	MedStar Georgetown University Hospital
NMED	Nuclear Materials Event Database
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer
SPECT/CT	Single-Photon Emission Computed Tomography/Computed Tomography