DMC

Harper University Hospital

DETROIT MEDICAL CENTER / WAYNE STATE UNIVERSITY

May 19, 2023

EA-22-135

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C.20555-001

NRC Region III Office
2443 Warrenville Road
Suite 210
Lisle, IL 60532

Re: Response to the Apparent Violations in Inspection Report No. 03002045/2021001(DRSS); EA-22-135 for VHS Harper-Hutzel Hospital, Inc.

To Whom it May Concern,

This letter is in response to the letter from the agency dated April 20, 2023, with Document Number EA-22-135, License number 21-04127-02, regarding the inspection conducted on March 1, 2021, and the additional in office review through March 7 2023 at the Detroit, Michigan facility. Please find our responses to each violation below.

1. ***During our inspection, it was found that the failure of the licensee's procedure to provide high confidence that administrations of Y-90 microspheres were in accordance with the written directive, due to (1) inadequate verification that administrations of Y-90 microspheres were in accordance with the treatment plan and written directive; and (2) inadequate determination of whether a medical event had occurred, is an apparent violation of 10 CFR 35.41(a)(2).***

    - The reason for the violation was that the pre- and post-treatment surveys to determine the residual fraction of the Y-90 microsphere dose was being done using a Bicron RSO-5 ionization chamber that was not sufficiently sensitive to measure less than 0.1 mR per hour. In addition, the effect of the background radiation where the surveys were performed was not taken into account. This only affected the rare cases where very small amounts of Y-90 microspheres were prescribed with the result that the residual fraction of the administered dose was apparently overestimated.
    - The corrective steps that have been taken include (1) the purchase and subsequent use of a new ionization chamber (Ludlum Model 9DP) sensitive enough to be in full compliance, and (2) modification of the Written Directive to include documentation of the residual fraction, delivered activity, and percent of the prescribed dose administered (copy of modified Written Directive attached).
    - These corrective steps will allow a more precise verification that the administration of Y-90 microspheres was in accordance with the treatment plan and written directive and allow documented verification by the authorized user to determine whether a medical event has occurred.

- The Written Directive was modified on March 2, 2021, the day after the date of inspection. The date when full compliance was achieved (with the purchase of the new ionization chamber and its subsequent use) was 5-10-2023.

2. ***During our inspection, it was found that the failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under its control that were received by an individual who was likely to receive, in 1 year from sources external to the body, a deep dose in excess of 10 percent of the limits in 10 CFR 20.1201(a) and was therefore required to use individual monitoring devices is an apparent violation of 10 CFR 20.1502(a)(1).***

    - The reason for the violation was that the primary individual (interventional radiologist) involved in performing Y-90 microsphere administrations worked at both Harper Hospital and another hospital and there was confusion as to which set of dosimetry badges should be worn. There was also insufficient monitoring as to when dosimetry badges were worn or not in the interventional radiology rooms.
    - The corrective steps that have been taken include (1) appointment of a specified individual to ascertain that dosimetry badges are correctly distributed to personnel and stored in easily accessible locations for their use, and then correctly returned to Landauer for evaluation, (2) addition to the "time-out" procedure for interventional radiology cases to require that all personnel are wearing their dosimetry badges before the procedure begins, (3) delegation of quarterly monitoring and reporting of dosimetry by Landauer, and (4) discussion with the AU in question regarding the importance of wearing his individual monitoring device (dosimetry badge) and wearing it correctly when RAM or radiation generating equipment is used.
    - The date when full compliance was achieved was 5/15/2023.

Thank you for reviewing our response. We are happy to respond to any further requests.

Sincerely,

MD

Richard Joyrich, M.D.
Chair, Radiation Safety Committee
VHS Harper-Hutzel Hospital
3990 John R Street
Detroit, MI 48201

Brady Dubois
CEO, Adult Central Campus
Detroit Medical Center
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DMC
Harper University Hospital

DEPARTMENT of NUCLEAR MEDICINE
WRITTEN DIRECTIVE FOR Y90 THERASPHERES

Patient Sticker

PATIENT INFORMATION:

Name:_____ Procedure Date:_____

DOB:_____ Diagnosis:_____

Allergies:_____ Weight: _____kg Referring Physician:_____

Prescribed Dose and Administration:

Radiopharmaceutical	Prescribed Dose	Route of Administration	Assayed Dose	Technologist Signature	Date/Time:	Verifying Technologist Signature	Date/Time:
^{90}Y TheraSphere	GBq		GBq				

Signature of Authorized User (Prescriber): _____ Date: _____ Time: _____

Dosage and Radiopharmaceutical Ordered: _____

Company:_____ Date Ordered: _____ Time Ordered:_____

Company Contact Person: _____ Ordering Personnel: _____

Calculated Delivered Activity

$$\text{Residual Activity} = \frac{\text{Average Final Surface Reading}}{\text{Initial Surface Reading}} = \_\_\_\_\_ = R$$

$$\text{Delivered Activity} = \text{Assayed Activity} * (1 - R) = \_\_\_\_\_ \text{GBq}$$

% of prescribed dose delivered: _____

Signature of Authorized User (Prescriber): _____ Date:_____Time:_____

Patient Identifier (Initial to confirm)	Technologist	Verifying Personnel
1) Patient name announced and verified against requisition/prescription/Written Directive		
2) Patient birth date announced and verified against requisition/prescription/Written Directive		
3) Patient wristband compared to requisition/prescription/ Written Directive and 1)and 2)		
4) Correct procedure verified		

Neg. Pregnancy confirmed by BHCG: Yes

LMP or Hysterectomy Date:_____

Breastfeeding: Yes No

Patient Signature:_____

Ryan Craffey

From: Joyrich, Richard <RJoyrich@dmc.org>
Sent: Friday, May 19, 2023 10:36 AM
To: Rhex Edwards; Ryan Craffey
Subject: [External_Sender] Responses to Apparent Violations
Attachments: NRC Response (1)-signed.pdf; NRC Response (2)-signed.pdf

To Whom It May Concern,

Attached are our two responses to the Apparent Violations in Inspection Report No. 03002045/2021001(DRSS); EA-22-135

The first response is for Enclosure 1 of the letter we received from you and the second one (marked OFFICIAL USE ONLY) is for Enclosure 2.

Please contact me for any needed further information.

Thank you,

Richard N. Joyrich, MD
Chair, Radiation Safety Committee
VHS Harper-Hutzel Hospital
3990 John R Street
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