



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

August 17, 2023

EA-22-135

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY-
\$8,750, NRC INSPECTION REPORT NO. 03002045/2021001(DRSS) AND
INVESTIGATION REPORT NO. 3-2022-004 – VHS HARPER-HUTZEL
HOSPITAL, INC.

Dear Dr. Joyrich:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) routine inspection of VHS Harper-Hutzel Hospital that began remotely on January 14, 2021. The inspection continued with an on-site visit to your facilities in Detroit, Michigan, on March 1, 2021, and additional in-office review through March 7, 2023. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. During the inspection, the NRC identified apparent safety and security violations. On March 30, 2023, Ryan Craffey, of my staff, conducted a final exit meeting by video teleconference between you, Jacqueline Arnold, and Joel Roger to discuss the results of the inspection. Inspection Report No. 03002045/2021001(DRSS) was issued on April 20, 2023. The publicly available portion of the inspection report, discussing the apparent safety violations, can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML23095A245. ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>. The security-related apparent violations were discussed in the non-public portion of the inspection report, because disclosure to unauthorized individuals could present a security vulnerability.

In addition, the NRC's Office of Investigations completed an investigation on December 16, 2022, to determine whether an yttrium-90 (Y-90) microspheres authorized user deliberately failed to wear dosimetry while performing NRC-regulated activities, and whether an individual deliberately failed to monitor a radiologist's occupational exposure to radiation sources under the control of the licensee. Based on the evidence developed during the investigation the NRC did not substantiate any deliberate actions involving the apparent violations.

In the April 20, 2023, letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a

Enclosure 2 contains Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 2, this transmittal letter, and Enclosures 1 and 3 are decontrolled.

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predecisional enforcement conference, by providing a written response, or by attending an alternative dispute resolution session before we made our final enforcement decision. In a letter dated May 19, 2023 (ML23139A250), you provided a written response to the apparent safety-related violations. In a separate letter dated May 19, 2023 (non-public), you provided a response to the apparent security-related violations. In an email dated May 19, 2023 (non-public), you provided a supplemental response to the apparent violations.

Based on the information developed during the inspection and investigation, and the information that you provided in your responses to the inspection report dated May 19, 2023, the NRC has determined that five violations of NRC requirements occurred and is proceeding with enforcement action. Violation A involves the failure to develop, implement, and maintain written procedures to provide high confidence that each administration of Y-90 microspheres was in accordance with the written directive as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.41(a)(2).

The NRC considers the failure of the microspheres procedure to direct staff to use an appropriate survey instrument when administering low dosages of Y-90, thereby, preventing an accurate determination of whether a medical event occurred is a significant safety concern. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The current Enforcement Policy is included on the NRC's web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$8,750 is considered for a SL III violation. Because your facility has been the subject of escalated enforcement actions within the last two inspections,¹ the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC determined that credit was not warranted for *Identification* because the issue was identified by the NRC during an inspection. The NRC determined that credit was warranted for *Corrective Action* that included the following: (1) purchased a Ludlum Model 9DP ionization chamber sensitive to determine the dosage delivered; (2) revised the microspheres procedure to require the use of the new ionization chamber and trained all involved staff on its use; and (3) modified the written directive form to include documentation of the residual fraction, delivered fraction and percent of the prescribed dose administered.

Therefore, to emphasize the importance of having appropriate procedures and survey instruments for the administration of low dosages of microspheres radioactive materials, I have been authorized after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) (Enclosure 1) in the base amount of \$8,750 for the Severity Level III violation. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has also determined that a Severity Level IV safety-related violation of NRC requirements occurred (Violation B in Enclosure 1). This violation involved the failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources during administrations of yttrium-90 microspheres, as required by 10 CFR 20.1502(a)(1). The violation is cited in the enclosed Notice (Enclosure 1) and the circumstances surrounding it are described

¹A Severity Level III security-related violation was issued on September 5, 2018 (EA-18-049).

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in detail in the subject inspection report. The violation is being cited in the Notice because it was identified by the inspector.

In addition, the NRC determined that three Severity Level IV security-related violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy and are cited in the enclosed non-public Notice (Enclosure 2) and the circumstances surrounding them are described in detail in the non-public portion of the subject inspection report. The violations are being cited in the Notice because they were identified by the inspector.

You may choose to pay the proposed civil penalty by submitting your payment, with the invoice enclosed to this letter (Enclosure 3), to the following address:

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

In addition, you may pay the proposed civil penalty in accordance with NUREG/BR-0254. The NUREG can be found on the NRC's web site at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0254/index.html>. When using NUREG/BR-0254 to pay the civil penalty, the invoice number should be used as the "enforcement action identifier" when submitting your payment through one of the approved methods listed in the brochure. The NRC may consider a request for additional time to pay the proposed civil penalty, including the option to enter into an installment agreement, if payment of the civil penalty as a lump sum in the required timeframe would pose a financial hardship. To request additional time to pay, you must submit a written request, with appropriate justification explaining your financial hardship, to NRCCollections.Resource@nrc.gov. All requests should be submitted in sufficient time to allow the NRC the ability to review your request for additional time to pay before the 30-day payment period expires.

If you disagree with this enforcement sanction, you may deny the violations, as described in the Notices, or you may request alternative dispute resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. **If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Diana Betancourt-Roldan at 630-810-4373 within 10 days of the date of this letter.** You may also contact both ICR and Diana Betancourt-Roldan for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the 30-day time period for payment of the civil

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penalty and the required written response, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03002045/2021001(DRSS), your letters dated May 19, 2023, and your email dated May 19, 2023. Therefore, you are not required to respond to this letter unless the description therein 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 Notices.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, and Enclosures 1 and 3 will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/index.html>.

However, Enclosure 2 to this letter contains Security-Related-Information in accordance with 10 CFR 2.390(d)(1) and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in Enclosure 2 will not be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS. If you choose to respond and Security-Related Information is necessary to provide an acceptable response, please mark the top of each page of your entire response "Security-Related Information – Withhold under 10 CFR 2.390" and follow the instructions for withholding in 10 CFR 2.390(b)(1).

If you have any questions concerning this matter, please contact Diana Betancourt-Roldan of my staff at 630-810-4373.

Sincerely,



Signed by Giessner, Jack
on 08/17/23

John B. Giessner
Regional Administrator

Docket No. 030-02045
License No. 21-04127-02

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty (Public)
2. Notice of Violation (Non-Public)
3. Civil Penalty Invoice No. EA-22-135

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Letter to R. Joyrich from J. Giessner dated August 17, 2023

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY-
\$8,750, NRC INSPECTION REPORT NO. 03002045/2021001(DRSS) AND
INVESTIGATION REPORT NO. 3-2022-004 – VHS HARPER-HUTZEL
HOSPITAL, INC.

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ADAMS Accession Number ML23200A143

OFFICE	RIII-EICS		RIII-DRSS		OE		NMSS	
NAME	KLambert:bw		REdwards		JPeralta		MBurgess	
DATE	7/20/2023		7/24/2023		8/7/2023		8/8/2023	
OFFICE	OGC (NLO)		RIII-EICS		RIII-ORA			
NAME	RAugustus		DBetancourt		JGiessner			
DATE	8/4/2023		8/17/2023		8/17/2023			

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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

VHS Harper-Hutzel Hospital, Inc.
Detroit, Michigan

Docket No. 030-02045
License No. 21-04127-02
EA-22-135

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted between January 14, 2021, and March 7, 2023, and an investigation completed on December 16, 2022, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I Violation Assessed a Civil Penalty

- A. Title 10 of the *Code of Federal Regulations* (10 CFR) 35.41(a)(2) requires that, for any administration requiring a written directive, the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Title 10 CFR 35.41(b)(2) requires that, at a minimum, the procedures required by paragraph (a) of this section must address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Title 10 CFR 35.41(b)(5) requires that, at a minimum, the procedures required by paragraph (a) of this section must address determining if a medical event, as defined in § 30.3045, has occurred.

Contrary to the above, on seven occasions between June 4, 2019, and September 9, 2020, the licensee administered yttrium-90 microspheres in individual quantities of less than or equal to 0.55 gigabecquerels using a procedure which did not provide high confidence that these administrations were in accordance with the written directive. Specifically:

1. The procedure did not adequately address verification that the administration is in accordance with the written directive, as it instructed staff to perform post-administration surveys of material remaining in the injection apparatus with a Bicon RSO-5 ionization chamber which did not possess the visual resolution necessary to provide high confidence that the administrations of these small doses were within 20 percent of the prescribed dose.
2. The procedure did not instruct staff to account for background dose rates in the area when using this instrument, further diminishing the ability to provide high confidence that these administrations were within 20 percent of the prescribed dose.

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3. The procedure did not adequately address determining if a medical event had occurred in these cases, as it did not consider post-administration surveys of material remaining in the injection apparatus in their evaluation of whether a medical event had occurred.

This is a Severity Level III violation (Enforcement Policy Section 6.3.c)
Civil Penalty - \$8,750 (EA-22-135)

II. Violation Not Assessed a Civil Penalty

- B. Title 10 CFR 20.1502(a)(1) requires, in part, that each licensee monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, on at least 109 occasions between January 1, 2018, and March 1, 2021, VHS Harper-Hutzel Hospital, Inc. failed 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. Specifically, an interventional radiologist did not wear individual monitoring devices supplied by the licensee while performing therapeutic administrations of yttrium-90 microspheres.

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 was achieved is already adequately addressed on the docket in Inspection Report No. 03002045/2021001(DRSS), the licensee's letters date May 19, 2023, and the licensee's email dated May 19, 2023. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a Reply to a Notice of Violation (EA-22-135), and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, Suite 210, 2443 Warrenville Road, Lisle, IL 60532-4352, and the Document Control Desk, Washington, DC 20555-0001.

The licensee may pay the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, through one of the following two methods:

1. Submit the payment with the enclosed invoice for Civil Penalty EA-22-135 issued to VHS Harper-Hutzel Hospital, Inc., to the following address:

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission

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P.O. Box 979051
St. Louis, MO 63197

OR

2. Submit the payment in accordance with NUREG/BR-0254.

The licensee may protest the imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: David Pelton, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, Suite 210, 2443 Warrenville Road, Lisle, IL 60532-4352 and the Document Control Center, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's 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 Security-Related Information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Security-Related Information is necessary to provide an

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acceptable response, please mark the top of each page of your entire response “Security-Related Information – Withhold under 10 CFR 2.390” and follow the instructions for withholding in 10 CFR 2.390(b)(1).

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

Dated this 17th day of August 2023.



VHS Harper-Hutzel Hospital, Inc.
3990 John R Street
Detroit, MI 48201



08/14/2023

Address/Customer Information

VHS Harper-Hutzel Hospital, Inc.
3390 JOHN R STREET
DETROIT, MI 48201

Customer Codes

Account Code: L000000891/1

Bill Information

Bill Number: EA-22-135
Amount Due: \$8,750.00
Due Date: 09/13/2023

Contact Us

Phone Number: 301-415-7554
Fax Number: 301-415-4135
Email Address: Fees.Resource@nrc.gov

Remit to Address

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

Bill Summary

Initial Charges	\$8,750.00
Discount	0.00
Surcharge	0.00
Interest Charges	0.00
Penalty Charges	0.00
Admin Charges	0.00
Bill Amount	\$8,750.00
Collected	0.00
Applied Credit	0.00
Adjustments	0.00
Amount Due	\$8,750.00

Credit Summary

Applied Credit	\$0.00
Unapplied Credit	0.00
Credit Total	\$0.00

Comments:

For questions, contact (301) 415-7554 or by email at Fees.Resource@nrc.gov. For NRC debt collection procedures, including interest and penalty provisions, see 31 U.S.C. 3717, 4 CFR 101-105, AND 10 CFR 15. Invoice if for Civil Penalty EA., issued to VHS Harper-Hutzel Hospital, Inc

Customer Information

L000000891/1
VHS Harper-Hutzel Hospital, Inc.
3390 JOHN R STREET
DETROIT, MI 48201

Change of Address:

Phone:

Remittance Information

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

This Payment References the following Bill:

EA-22-135

Outstanding Amount Due:

\$8,750.00

Amount Enclosed:
