



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

March 25, 2024

EA-23-108

Beth Tharp
Senior Vice President, Hospital Acute
Care Services
Community Health Network, Inc.
1500 N. Ritter Ave.
Indianapolis, IN 46219

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -
\$27,000, NRC ROUTINE INSPECTION REPORT NO. 03001625/2022001 (DRSS) -
COMMUNITY HEALTH NETWORK, INC.

Dear Beth Tharp:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on December 5, 2022, through December 7, 2022, at your Indianapolis, Indiana facilities with continued in-office review through October 25, 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, three apparent violations of NRC requirements were identified. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you during an exit meeting on October 25, 2023. Inspection Report No. 03001625/2022001 (DRSS) was issued on November 9, 2023, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML23279A052. ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>.

On January 18, 2024, a Predecisional Enforcement Conference (PEC) was conducted at the NRC's Region III office with Erin Bell of your staff to discuss the apparent violations, their significance, their root causes, and your corrective actions. A portion of the conference was closed to public observation because we discussed security-related information.

Based on the information developed during the inspection and the information that was provided during the conference, the NRC has determined that three violations of NRC requirements occurred and is proceeding with enforcement action. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. Violation A involves the failure to maintain control and constant surveillance of a high dose rate (HDR) unit containing iridium-192 as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1802. Violation B involves the failure to prepare written directives that were dated and signed by an authorized user before administration of iodine-131 (I-131) sodium iodide greater than

1.11 megabecquerels (30 microcuries) as required by 10 CFR 35.40(a). Violation C involves the failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and assign a shallow-dose equivalent for an individual's skin receiving the highest exposure as required by 10 CFR 20.1502(a)(1) and 20.1201(c).

The violations above represent significant safety and security concerns to the NRC because such violations could result in uncontrolled and unmonitored materials in the public domain, including unknowing exposures to members of the public (no known exposures occurred); incorrect administrations of I-131; and unknown exposures to occupational workers, including the potential for overexposures (no known overexposures occurred). Therefore, each of these violations has been categorized in accordance with the NRC Enforcement Policy at Severity Level (SL) 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 \$9,000 is being considered for each SL III violation for a total amount of \$27,000.

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 NRC Enforcement Policy. Credit for identification is not warranted because violation A was identified through an event (the unsecured HDR unit was a self-revealing problem), and violations B and C were NRC-identified during the inspection. We recognize your commitment to cultivating a safety culture within your institution as discussed during the PEC. We encourage you to continue your management commitment in recognizing that self-identification and reporting are vital aspects of an effective radiation safety program.

Credit for corrective actions is warranted for all three violations (A, B and C). However, your corrective actions for violation C need to be formally submitted on the docket (please see additional details below regarding the need for a formal response to this letter). Corrective actions for violation A included (1) conducting remedial training with the Radiation Oncology Department on the security requirements of HDR devices; and (2) requiring a physicist to be present during the time that the afterloader is being serviced by the vendor's engineer and to lock the HDR unit storage cabinet after servicing. Corrective actions for violation B included (1) developing written directive training and retrained all nuclear medicine technologists as well as the I-131 authorized users to remind them of the regulations and requirements; (2) developing a new generic written directive for use by the authorized users, distributed the new written directive to the technologists, and placed a copy on your Teams page; and (3) having one of your part-time nuclear medicine physicists do at least one audit at each site per year. Correction actions for violation C, which were discussed during the closed portion of the PEC, included (1) providing remedial training to the individual on the proper use of extremity dosimeters; and (2) ensuring that all users understand that the policy is to always wear dosimetry, including extremity dosimetry, during treatments involving radioactive materials or sources of radiation.

Therefore, to emphasize the importance of securing licensed material, having written directives, wearing assigned dosimetry, and promptly identifying violations, and in recognition of your

¹ A Severity Level III violation was issued on April 3, 2023 (EA-22-091) for the failure to implement procedures involving administrations of yttrium-90.

previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice). For each of the three violations, the base civil penalty of \$9,000 for a SL III violation is being assessed.

Issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its web site at http://www.nrc.gov/reading_rm/doc_collections/enforcement/actions/.

You may choose to pay the proposed civil penalty, or the cumulative amount of the civil penalties if more than once civil penalty is proposed, by submitting your payment, with the invoice enclosed to this letter, 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 penalties in accordance with [NUREG/BR-0254](#). 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 violation, as described in the Notice, 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 Bentancourt-Roldan at (630) 810-4373 within 10 days of the date of this letter.** You may also contact both ICR and Ms. 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 penalties and the required written response, as identified in the enclosed Notice, until the ADR process is completed.

You are required to respond to this letter to receive corrective action credit for violation C and should follow the instructions specified in the enclosed Notice when preparing your response. The response must confirm the corrective actions described above for violation C, which were discussed in the closed portion of the PEC. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

For violations A and B, the NRC has concluded that information regarding (1) the reason for the violations, or if contested, the basis for disputing the violations; (2) the corrective steps that have been taken and the results achieved; and (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. 03001625/2022001(DRSS), Community Health's presentations at the PEC held on January 18, 2024 (ML24067A056), and Community Health's January 25, 2024 (ML24067A031), written response. Therefore, you are not required to respond to this letter with respect to violations A and B 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 Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's ADAMS, accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your 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 withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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 you choose to respond and security-related information is necessary to provide an acceptable response, please mark your entire response Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b).

B. Tharp

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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 03/25/24

John B. Giessner
Regional Administrator

Docket No. 030-01625
License No. 13-06009-01

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalties
Civil Penalty Invoice No. EA-23-108
NUREG/BR-0254 Payment Methods
(Licensee only)

cc w/encl: Erin Bell, MHP, RSO
Derek McMichael, Vice-President
Operations
State of Indiana

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Community Health Network, Inc.
Indianapolis, Indiana

Docket No. 030-01625
License No. 13-06009-01
EA-23-108

During an NRC inspection conducted on December 5, 2022, through December 7, 2022, with continued in-office review through October 25, 2023, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose civil penalties 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 specific violations and associated civil penalties are set forth below:

- A. Title 10 of the *Code of Federal Regulations* (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, from February 2, 2022, through February 4, 2022, the licensee failed to control and maintain constant surveillance of licensed material that was in a controlled area and that was not in storage. Specifically, the licensee did not control or maintain constant surveillance of approximately 5 curies (198 gigabecquerels) of iridium-192 that was not in storage and was located in a treatment vault which was a controlled area.

This is a Severity Level III violation (NRC Enforcement Policy Section 6.7).
Civil Penalty - \$9,000 (EA-23-108)

- B. Title 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of iodine-131 sodium iodide greater than 1.11 megabecquerels (30 microcuries).

Contrary to the above, between December 15, 2020, and June 21, 2022, the licensee failed to prepare written directives that were dated and signed by an authorized user before administration of iodine-131 sodium iodide greater than 1.11 megabecquerels (30 microcuries). Specifically, seven patients received administrations of iodine-131 sodium iodide with an activity between 1.95 millicuries (72.15 megabecquerels) and 2.2 millicuries (81.4 megabecquerels) without a written directive.

This is a Severity Level III violation (Enforcement Policy Section 6.3).
Civil Penalty - \$9,000 (EA-23-108)

- C. Title 10 CFR 20.1502(a)(1) requires, in part, that each licensee 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).

Enclosure

Title 10 CFR 20.1201(a)(2)(ii) requires, in part, that the annual limit to the skin of the extremities is a shallow-dose equivalent of 50 rem (0.5 Sievert).

Title 10 CFR 20.1201(c) requires, in part, that the assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

Contrary to the above, for periods between January 2020 and December 2022, the licensee failed to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and did not 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)(2)(ii). Specifically, an individual whose occupational exposure to licensed and unlicensed sources of radiation was likely to exceed 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii) often failed to wear their supplied extremity dosimeter, thereby preventing the licensee from monitoring their occupational shallow-dose equivalent exposure to the skin of the extremity (hand). Additionally, the licensee failed to assign a shallow-dose equivalent for the individual that was the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

This is a Severity Level III violation (Enforcement Policy Section 6.7)
Civil Penalty - \$9,000 (EA-23-108)

For violation C, pursuant to the provisions of 10 CFR 2.201, Community Health Network, Inc., is hereby required to submit a written statement or explanation to 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, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 and the Document Control Desk, Washington, DC 20555-0001, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-23-108" and should include for violation C (1) the corrective steps that have been taken and the results achieved; (2) the corrective steps that will be taken; and (3) the date when full compliance will be achieved.

Your response may reference or include previous docketed correspondence if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

The NRC has concluded that information regarding the reason for violations A and B, 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. 03001625/2022001(DRSS), Community Health's presentations at the PEC held on January 18, 2024, and Community Health's January 25, 2024, written response. 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, include your response in the Reply to a Notice of Violation required for violation C discussed above.

The Licensee may pay the civil penalties 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 Penalties EA-23-108 issued to Community Health Network, Inc. (Licensee), to the following address:

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
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 penalties 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 penalties. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, 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 penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, 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 civil penalties.

Upon failure to pay any civil penalties which subsequently have 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 penalties, 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 penalties, 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, and the Document Control Desk, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the ADAMS, accessible from the NRC Web site 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 personal privacy, proprietary, or security-related 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 withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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 you choose to respond and security-related Information is necessary to provide an acceptable response, please mark your entire response Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)

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

Dated this 25th day of March 2024.



03/21/2024

Address/Customer Information

Community Health Network, Inc.
1500 N. RITTER AVENUE
INDIANAPOLIS, IN 46219

Customer Codes

Account Code: L00000672/1

Bill Information

Bill Number: EA-23-108
Amount Due: \$27,000.00
Due Date: 04/20/2024

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	\$27,000.00
Discount	0.00
Surcharge	0.00
Interest Charges	0.00
Penalty Charges	0.00
Admin Charges	0.00
Bill Amount	\$27,000.00
Collected	0.00
Applied Credit	0.00
Adjustments	0.00
Amount Due	\$27,000.00

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. For questions, contact the NRC Financial Services and Operations Branch at (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.

If this invoice is related to an Order Imposing a Civil Penalty, Community Health Network, Inc. is required to pay the Civil Penalty within 30 days of the Order date. If payment is in response to a Notice of Violation and Proposed Imposition of a Civil Penalty, please follow the instructions in the Notice. The NRC may consider a request for additional time to pay the Civil Penalty, including the option to enter into an installment agreement, if appropriate. All requests for additional time to pay an invoice must be submitted in writing, with appropriate justification, to NRCCollections.Resource@nrc.gov, and should be submitted sufficiently ahead of time to allow the NRC time to review the request for additional time to pay within the 30-day payment period. This Invoice is related to the Civil Penalty proposed or imposed under EA-23-108 issued to Community Health Network, Inc. Please include this reference number on your payment method (see attached Payments Methods Brochure).

Customer Information

L00000672/1
Community Health Network, Inc.
1500 N. RITTER AVENUE
INDIANAPOLIS, IN 46219

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-23-108

Outstanding Amount Due: \$27,000.00

Amount Enclosed: _____