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

November 9, 2023

EA-23-108

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

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001625/2022001(DRSS) – COMMUNITY HEALTH NETWORK, INC.

Dear Beth Tharp:

On December 5, 2022, through December 7, 2022, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Indianapolis, IN, 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. The in-office review included a review of your iodine-131 program, security of radioactive materials, and occupational dose monitoring program. The enclosed inspection report and security addendum present the results of the inspection. The inspector discussed the preliminary inspection findings with your staff at the conclusion of the on-site portion of the inspection on December 7, 2022. Preliminary inspection findings were presented to you and your staff on October 4, 2023. A final exit meeting was conducted virtually with you and your staff on October 25, 2023.

This inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions in your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, three apparent violations of NRC requirements were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. One apparent violation was of a security-related nature. Details of the security-related apparent violation are discussed

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

in Enclosure 2. The second apparent violation concerned the licensee's failure 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) as required by 10 CFR 35.40(a). The third apparent violation concerned the licensee's failure 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). Details of the safety-related apparent violation are discussed in Enclosure 1. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the meeting conducted by Elizabeth Tindle-Engelmann on October 4, 2023.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violations addressed in this inspection report and security addendum within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. **Please contact Rhex Edwards at (630) 829-9722 or Rhex.Edwards@nrc.gov within 10 days of the date of this letter of your intended response or request.** A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violations in Inspection Report No. 03001625/2022001(DRSS); EA-23-108," and should include, for the apparent violations: (1) the reason for the apparent violations, or, if contested, the basis for disputing the apparent violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your response should be sent to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to

any corrective actions taken or planned. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations.

The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html.

You may also request 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 party (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 program can be obtained 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. **Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. In addition, if you choose ADR, please also contact Rhex Edwards at the telephone number or email address listed above.**

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report and security addendum may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with the NRC's "Agency Rules of Practice and Procedure" in 10 CFR 2.390," a copy of this letter and Enclosure 1 will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your written response to the apparent violation of safety requirements, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

However, Enclosure 2 and any response you provide will not be made available electronically for public inspection because of the security-related information that is or would likely be contained in each. If responding to Enclosure 2, please separate the response from the response to the apparent violation described in Enclosure 1 and mark the former as Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)(1). In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for your response.

Please feel free to contact Elizabeth Tindle-Engelmann of my staff if you have any questions regarding this inspection. Elizabeth can be reached at 630-829-9681 or Elizabeth.Tindle-Engelmann@nrc.gov.

Sincerely,

Signed by Curtis, David
on 11/09/23

David Curtis, Director
Division of Radiological Safety and Security

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

Enclosures:
1. Inspection Report No. 03001625/2022001(DRSS) (Public)
2. Security Addendum (Non-public)

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

Letter to B. Tharp from D. Curtis, dated November 9, 2023.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001625/2022001(DRSS) – COMMUNITY HEALTH NETWORK, INC.

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ADAMS Accession Number: ML23279A052

OFFICE	RIII-DRSS	RIII-DRSS	HQ-NMSS	HQ-OE
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DATE	10/25/23	10/26/23	11/6/23	11/7/23

OFFICE	HQ-OE	RIII-EICS	RIII-DRSS	
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DATE	11/8/23	11/8/23	11/9/23	

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01625
License No.	13-06009-01
Report No.	03001625/2022001(DRSS)
EA No.	EA-23-108
Licensee:	Community Health Network, Inc.
Locations:	1500 N. Ritter Ave. Indianapolis, IN 7150 Clearvista Dr. Indianapolis, IN 7979 N Shadeland Indianapolis, IN 8075 N Shadeland Ave. Indianapolis, IN 1400 N Ritter Ave. Indianapolis, IN
Inspection Dates:	Onsite December 5, 2022 - December 7, 2022; in-office review through October 25, 2023.
Exit Meeting Date:	October 25, 2023
Inspector:	Elizabeth Tindle-Engelmann, Health Physicist
Approved By:	Rhex Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

Enclosure 1

EXECUTIVE SUMMARY

Community Health Network, Inc.
NRC Inspection Report 03001625/2022001(DRSS)

This was an announced routine inspection at Community Health Network, Inc. (CHN). The licensee was a multi-site medical institution with facilities in Indianapolis, Indiana. The U.S. Nuclear Regulatory Commission (NRC) License No. 13-06009-01 authorized CHN to possess and use byproduct material for various medical uses including diagnostic and therapeutic radiopharmaceuticals, manual brachytherapy, high dose rate (HDR) remote afterloading brachytherapy, and the medical use of yttrium-90 (Y-90) microspheres as permitted by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.1000.

The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC rules, regulations, and the conditions of the license. Based on the results of this inspection, three apparent violations were identified. The circumstances surrounding a security-related apparent violation are described in the non-public Security Addendum to this Inspection Report (IR). The second apparent violation concerns the licensee's failure to prepare written directives that were dated and signed by an authorized user (AU) before administration of iodine-131 (I-131) sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)) as required by 10 CFR 35.40(a). The third apparent violation concerns the licensee's failure 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).

REPORT DETAILS

1 Program Overview and Inspection History

1.1 Inspection Scope

The inspector reviewed the license application and supporting documents. Additional information was gathered through direct observation of licensed activities, interviews with the licensee's staff, a review of selected records, and a tour of the facilities.

1.2 Observations and Findings

CHN was authorized under NRC License Number 13-06009-01 to possess and use diagnostic and therapeutic radiopharmaceuticals as permitted by 10 CFR 35.100 – 300, sealed sources for brachytherapy as permitted by 10 CFR 35.400, HDR remote afterloading brachytherapy as permitted by 10 CFR 35.600, the medical use of Y-90 microspheres as permitted by 10 CFR 35.1000, and byproduct material permitted by 10 CFR 31.11 for use in in-vitro studies.

The licensee had multiple licensed facilities located in Indianapolis, Indiana: Community Hospital East, Community Hospital North, Community Hospital South, Community Regional Cancer Center South, Community Cancer Center North, and multiple outpatient clinics. The licensee maintained multiple active nuclear medicine departments that routinely performed diagnostic and therapeutic administrations of radiopharmaceuticals and microspheres. All therapy procedures were performed on an outpatient basis. Additionally, the licensee had multiple Radiation Oncology Departments that performed brachytherapy procedures. The licensee had a full time Radiation Safety Officer (RSO) that provided radiation safety support and oversight. Additionally, the licensee maintained an active Radiation Safety Committee (RSC) to provide oversight of licensed activities.

The licensee's inspection history is summarized below:

- A limited scope reactive inspection was conducted from April 14, 2023, through September 11, 2023, to review the circumstances surrounding a Y-90 microspheres medical event. One severity level IV violation was identified and subsequently issued to the licensee on September 29, 2023. The violation involved the licensee's failure to implement written procedures to provide high confidence that each administration of Y-90 microspheres was in accordance with the written directive, as required by 10 CFR 35.41(a)(2). Specifically, the licensee implemented the manufacturer's instructions for use, titled "SIR-Spheres® microspheres V-vial Instructions for use", which required, in part, that the user withdraw the volume of SIR-Spheres microspheres that will provide the intended patient-specific activity. However, on April 10, 2023, the licensee failed to follow the manufacturer's instructions for use when a volume of SIR-Spheres microspheres with 2.34 Gigabecquerels (GBq) (63.2 millicuries (mCi)) of activity was withdrawn, rather than the intended volume of SIR-Spheres microspheres with the intended patient-specific activity of 1.6 GBq (43.2 mCi). The error was caused by a data entry mistake on the spreadsheet which instructs the user on

how much volume to withdraw for the patient-specific activity. This was dispositioned as a severity level IV violation since it was an isolated failure to follow procedures for administrations requiring a written directive that did not demonstrate programmatic weaknesses in implementation and had limited consequences as a medical event.

- A limited scope reactive inspection was conducted from November 23, 2021, through December 2, 2022, to review the circumstances surrounding a Y-90 microspheres medical event. One severity level III violation was identified and subsequently issued to the licensee on April 3, 2023. The violation involved the licensee's failure to implement written procedures to provide high confidence that each administration of Y-90 microspheres was in accordance with the written directive, as required by 10 CFR 35.41(a)(2). Specifically, the licensee implemented the manufacturer's instructions for use, titled "SIR-Spheres® microspheres V-vial Instructions for use", which specifies, in part, that the licensee insert a short 25-gauge needle through the rubber septum of the V-vial until it just pierces the septum to create a vent during the dosage preparation. However, on November 16, 2021, and various prior dates, the licensee used a 20-gauge needle in lieu of the specified 25- gauge needle which prevented the septum of the V-vials from resealing. The V-vial septum failure led to a loss of pressure in the administration system. The licensee applied an adhesive to the V-vial septum to regain pressure. The adhesive prevented the licensee from maneuvering the needles to complete the administration, thus preventing the licensee from administering the prescribed activity of Y-90 microspheres. This was dispositioned as a severity level III violation since it was a nonisolated failure to follow procedures for administrations requiring a written directive.
- A limited scope reactive inspection was conducted from November 15, 2021, through July 14, 2022, to review the circumstances surrounding a dose to an embryo and no violations were identified.
- A routine inspection of the licensee was conducted in January of 2020 and no violations were identified.

2 Radiation Safety Program

2.1 Inspection Scope

On December 5 – 7, 2023, the inspector visited five of CHN's facilities to review the implementation of the licensee's radiation safety program. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with NRC rules, NRC regulations, and the conditions of the license. The inspector toured the facilities, observed licensed activities, conducted interviews, and reviewed selected records.

2.2 Observations and Findings

The inspector toured five facilities and observed the following tasks: dose calibrator quality control testing, dosage preparation and administration, HDR spot checks, HDR treatment administration, surveys, and Y-90 preparation and administration. The licensee demonstrated the following tasks: decay-in-storage procedures, instrument quality control, and receipt of radioactive material. The inspector reviewed a sample of

records including the following items: annual program reviews, decay in storage logs, dose calibrator calibrations, dosimetry results, HDR spot checks, HDR full calibrations, incident reports, instrument calibrations, patient release instructions and records, RSC meeting minutes, sealed source inventories and leak tests, shipping and receiving logs, spill reports, surveys, training, and written directives.

Based on the inspection, there were three apparent violations of NRC requirements that are being considered for escalated enforcement.

Apparent violation of 10 CFR 35.40(a)

On December 15, 2020, October 5, 2021, February 16, 2021, February 23, 2021, and June 21, 2022, the licensee's nuclear medicine staff was unable to obtain iodine-123 (I-123) due to supply chain issues. In order to prevent cancelation of the study, the staff, in consultation with an AU, ordered I-131 sodium iodide from their radiopharmacy for uptake studies. In each case, the nuclear medicine staff received verbal approval from one of the AUs. However, no written directives were prepared for seven administrations of approximately 74 MBq (2 mCi) of I-131 sodium iodide that occurred on the five aforementioned dates.

While the licensee had a procedure that stated written directives for the administration of I-131 sodium iodide greater than 1.11 MBq (30 uCi) were required, the licensee's nuclear medicine staff and lead AU were unaware of the activity-based threshold for I-131 sodium iodide administrations. Their understanding was that uptake studies did not require written directives even when conducted with I-131. This is an apparent violation of 10 CFR 35.40(a) which requires, in part, that a written directive must be dated and signed by an AU before the administration of I-131 sodium iodide greater than 1.11 MBq (30 uCi).

Upon identification of the issue, the inspector discussed whether there were any radiation safety concerns for the patients based on the use of I-131 in place of I-123 with the AU. The AU indicated that this was an appropriate clinical use of I-131 and no medical concerns were noted.

The licensee's immediate corrective actions included implementing training for staff and AUs on the requirements for written directives. The inspector reviewed a large sample of administrations requiring written directives during the inspection period and found no other concerns.

Apparent Violation of 10 CFR 20.1502(a)(1)

During a review of the dosimetry records, the inspector observed that one AU of Y-90, 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. The individual's failure to wear the monitoring devices prevented the licensee from monitoring their occupational shallow-dose equivalent exposure to the skin. This is an apparent violation of 10 CFR 20.1502(a)(1) which 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)(2)(ii).

Upon identification of the apparent violation, the licensee estimated the extremity exposure for the AU to be 4894 mrem for calendar year 2021 and 4654 mrem for calendar year 2022. As a corrective action, the licensee provided remedial training to the individual on the proper use of extremity dosimeters.

2.3 Conclusions

Three apparent violations were identified and are being considered for escalated enforcement. One apparent violation is security-related and is described in the non-public Security Addendum to this IR. The second apparent violation concerns the licensee's failure to prepare written directives that were dated and signed by an AU before administration of iodine-131 (I-131) sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)) as required by 10 CFR 35.40(a). The third apparent violation concerned the licensee's failure 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).

3 Independent Radiation Measurements

Independent radiation surveys were conducted at the inspected facilities. The survey results were consistent with the licensee's postings, the licensee's survey results, and applicable regulatory limits.

Instrumentation:	Model: RadEye G Serial Number: 30652 Calibration Expiration: July 14, 2023

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on December 7, 2022, and virtually on October 4, 2023. Upon completion of the in-office review, a virtual exit meeting was held on October 25, 2023, with the licensee. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented and stated corrective actions have been implemented.

LIST OF PERSONNEL CONTACTED

^#* Erin Bell, MHP, RSO
* Patrick Bryne, Consultant
# Nicole Carlisle, Executive Director Oncology Services
#* Colleen DesRosiers, Network Chief Therapy Physicist
Tom Jessie, Director of Imaging CHE
^# Cory McCallie, Director of Imaging CHN
^#* Derek McMichael, VPO Hospital Administrator and VP of Medical Imaging
Kate Myers, Director of Imaging CHS
Kristina Oehlman, Manager Radiation Oncology, Cancer Center East
Jen Stigler, Manager Radiation Oncology, Cancer Center North
^#* Beth Tharp, SVP, Hospital Acute Care Services
Ricky Wessel, Manager of Imaging CHE

^ Attended inspection debrief on December 7, 2022.
# Attended virtual meeting on October 4, 2023.
* Attended virtual exit meeting on October 25, 2023.

LIST OF ACRONYMS AND ABBREVIATIONS USED

AU	authorized user
CHN	Community Health Network
GBq	Gigabecquerels
HDR	high dose rate
I-123	iodine-123
I-131	iodine-131
IR	Inspection Report
MBq	Megabecquerels
mCi	millicurie
NRC	Nuclear Regulatory Commission
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
uCi	microcurie
Y-90	yttrium-90
10 CFR	Title 10 of the *Code of Federal Regulations*

INSPECTION PROCEDURES USED

IP 87130 – Nuclear Medicine Programs
IP 87132 – Brachytherapy Programs