



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

April 3, 2023

EA-22-091
NMED No. 210491 (closed)

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

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO.
03001625/2021002(DRSS) – COMMUNITY HEALTH NETWORK, INC

Dear Beth Tharp:

This letter refers to the US Nuclear Regulatory Commission (NRC) inspection conducted on November 23, 2021, at your Community Hospital North location in Indianapolis, Indiana, with continued in-office review through December 2, 2022. The purpose of the inspection was to review the circumstances surrounding a medical event involving an yttrium-90 (Y-90) microsphere therapy that was reported to the NRC on November 17, 2021. An exit meeting was held on December 2, 2022, with you to discuss the apparent violation involving the failure to implement written procedures to provide high confidence that each administration of Y-90 microspheres was in accordance with the written directive. Inspection Report No. 03001625/2021002(DRSS) was issued on December 28, 2022. The report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML22343A245. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated January 17, 2023, (ML23026A078) you provided a response to the apparent violation that included corrective actions. You also provided a supplemental response in an email dated February 16, 2023 (ML23052A021). In the January 17, 2023, response you stated that you did not believe a violation of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.41(a)(2) was applicable because the physicist procedure was followed. The physicist procedure referenced in your January 17, 2023, letter did not include instructions for preparing Y-90 dosages. To comply with the requirements of 10 CFR 35.41(a)(2), which requires, in part, that licensees develop and implement procedures for administrations requiring a written directive, Community Health Network committed in its license to follow the manufacturer's instructions for delivery and use of Y-90 microspheres. The manufacturer's instructions for use of the v-vial, contained in the device package insert, prescribed the use of a short 25-gauge needle to vent the v-vial. However, Community Hospital North staff used a larger 20-gauge needle contrary to the manufacturer's instructions.

Based on the information developed during the inspection and the information that you provided in your responses to the inspection report dated January 17, 2023, and your email dated February 16, 2023, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to implement written procedures to provide high confidence that each administration of Y-90 is in accordance with the written directive. Community Hospital North staff routinely failed to use the appropriate gauged needle specified in the manufacturer's instructions when venting the vial containing Y-90. This failure to implement the manufacturer's instructions is a significant safety issue that resulted in a medical event. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$8750 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Corrective actions included the following: (1) updated the Physicist Procedure by providing greater detail on the dose preparation and delivery; (2) updated Y-90 program information, including policies, calculation worksheets, and written directive, which were provided to nuclear medicine staff and copies placed in the hot labs where Y-90 doses are drawn; (3) trained the nuclear medicine lead technologists on the new Y-90 procedures; and (4) switched to the new SIROS system that includes vent needles. Additionally, you will be submitting a license amendment to revise your current license commitments relative to your Y-90 program.

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation 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/>).

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No 03001625/2021002(DRSS), your letter dated January 17, 2023, and your email dated February 16, 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 Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room and in 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 or proprietary 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, 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 information, 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 have any questions concerning this matter, please contact Diana Betancourt-Roldan, Enforcement Officer, of my staff, at 630-810-4373 or diana.betancourt-roldan@nrc.gov.

Sincerely,



Shuaibi, Mohammed signing on behalf
of Giessner, Jack
on 04/03/23

John B. Giessner
Regional Administrator

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

Enclosure: Notice of Violation

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

Letter to B. Tharp from J. Giessner dated April 3, 2023.

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO. 03001625/2021002(DRSS) – COMMUNITY HEALTH NETWORK, INC

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NOTICE OF VIOLATION

Community Health Network, Inc.
Indianapolis, Indiana

Docket No. 030-01625
License No. 13-06009-01
EA-22-091

During a US Nuclear Regulatory Commission (NRC) inspection conducted on November 23, 2021, with continued in-office review through December 2, 2022, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.41(a)(2) states 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.

Condition 13.A. of Amendment 103 of License Number 13-06009-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated December 23, 2013 (ML13365A143).

The application dated December 23, 2013, states, in part, that other than change in the materials requested, the licensee will follow those procedures as stated in their application dated July 15, 2003, and the facsimiles, letters, and emails as listed on Amendment 81 of License Number 13-06009-01.

Condition 20.C. of Amendment 81 of License Number 13-06009-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated May 23, 2006 (ML061560145). Section VII, Operating Procedures, of the letter dated May 23, 2006, states, in part, that the device package insert instructions for delivery and use will be followed.

The device package insert includes the manufacturer's instructions for use, titled "SIR-Sphere® microsphere V-Vial Instructions for use." The manufacturer's instructions for use require, in part, that the user 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.

Contrary to the above, prior to and including November 16, 2021, Community Health Network, Inc., failed to implement written procedures to provide high confidence that administrations of yttrium-90 microspheres were in accordance with the written directive. Specifically, the licensee failed to follow the manufacturer's instructions for use when a 20-gauge needle, rather than the prescribed 25-gauge needle, was inserted through the rubber septum of the v-vial until it just pierced the septum to create a vent when preparing a dosage of yttrium-90 microspheres.

This is a Severity Level III violation (Enforcement Policy Section 6.3.).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03001625/2021002(DRSS), the licensee's letter dated January 17, 2023, and the licensee's email dated February 16, 2023. However, you are required to submit a written

Enclosure

statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-22-091," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, 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 Agencywide Documents Access and Management System (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 or proprietary information so that it can be made available to the Public without redaction.]

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

Dated this 3rd day of April 2023.