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

July 27, 2022

EN 55563
NMED No. 210467 (Closed)

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

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001625/2021001(DNMS) – COMMUNITY HEALTH NETWORK, INC.

Dear Beth:

On November 15, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at Community Hospital South located in Indianapolis, Indiana, with continued in-office review through July 14, 2022. The purpose of the inspection was to review the circumstances surrounding the dose to an embryo following an iodine-131 treatment that was administered on September 30, 2021. The event was reported to the NRC on November 5, 2021. The in-office review included a review of the estimated dose to the embryo. Elizabeth Tindle-Engelmann of my staff conducted a virtual exit meeting with you and your staff on July 14, 2022, to discuss the inspection findings. This letter presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Within the scope of this inspection, the NRC did not identify any violations of NRC requirements.

In accordance with the NRC's "Rules of Practice," in 10 CFR 2.390, a copy of this letter, its enclosure, and any response you provide 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, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

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.

Sincerely,

Warren, Geoffrey signing on behalf
of Kunowski, Michael
on 07/27/22

Michael A. Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

Enclosure: NRC Inspection Report
03001625/2021001

cc (w/encl): Erin Bell, MHP, Radiation
Safety Officer
State of Indiana

Letter to B. Tharp from M. Kunowski dated July 27, 2022.

SUBJECT: NRC INSPECTION REPORT NO. 03001625/2021001(DNMS) – COMMUNITY HEALTH NETWORK, INC.

DISTRIBUTION w/encl:
Jack Giessner
Mohammed Shuaibi
David Curtis
Jared Heck
Joseph Nick
Michael Kunowski
Diana Betancourt-Roldan
Kenneth Lambert
MIB Inspectors

ADAMS Accession Number: ML22207B800

OFFICE	RIII-DNMS		RIII-DNMS					
NAME	ETindle-Engelmann:bw		GWarren for MKunowski					
DATE	7/26/2022		7/27/2022					

OFFICIAL RECORD COPY

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01625
License No.	13-06009-01
Report No.	03001625/2021001(DNMS)
EN No./NMED No.	55563/210467
Licensee:	Community Health Network, Inc.
Facility:	1402 E. County Line Road South Indianapolis, Indiana
Inspection Dates:	Onsite November 15, 2021 In-office review through July 14, 2022
Exit Meeting Date:	July 14, 2022
Inspector:	Elizabeth D. Tindle-Engelmann, Health Physicist
Approved By:	Michael A. Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Community Health Network, Inc.
NRC Inspection Report 03001625/2021001(DNMS)

This was an announced reactive inspection at Community Health Network, Inc.'s (CHN's) Community Hospital South. The licensee was a multi-site medical institution with five facilities in Indianapolis, Indiana. The U.S. Nuclear Regulatory Commission (NRC) License Number 13-06009-01 authorized CHN to possess and use byproduct material for various diagnostic and therapeutic uses including the medical uses of iodine-131 (I-131) as permitted by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.300 as unsealed byproduct material for which a written directive is required.

The scope of the inspection was limited to the review of the circumstances surrounding a dose to an embryo that was reported to the NRC on November 5, 2021, and the licensed activities associated with the use of I-131 at CHN's Community Hospital South. The event involved a possible dose to an embryo greater than 50 millisievert (mSv) (5 rem) dose equivalent from an administration of byproduct material to an individual on September 30, 2021. Specifically, a patient received approximately 148 millicuries (mCi) of I-131 sodium iodine and subsequently discovered that they were pregnant. The pregnancy was reported to the licensee on November 4, 2021. At the time of the inspection and the licensee's telephone notification, the conception date of the embryo was unknown but presumed to be sometime in the range of 1 day before to 10 days after the administration. The dose to the embryo was estimated to be between 394.3 mSv (39.43 rem) and 1.7 mSv (0.17 rem). It was later determined that the conception date was 7 days after the administration and the dose to the embryo was estimated to be 1.7 mSv (0.17 rem). The licensee submitted a written report to the NRC on November 11, 2021, and an addendum based on subsequently obtained information on November 17, 2021.

The licensee implemented preventative measures to reduce the risk of recurrence of a similar type of embryo exposure.

Based on the results of this inspection, no violations were identified.

REPORT DETAILS

1 Program Overview and Inspection History

1.1 Inspection Scope

The scope of this inspection was limited to the review of use I-131 as permitted by 10 CFR 35.300 as unsealed byproduct material for which a written directive is required and the circumstances surrounding a dose to an embryo that occurred at CHN's Community Hospital South.

The inspector reviewed the license application and supporting documents within the scope of the inspection. Additional information was gathered through interviews with the licensee's staff.

1.2 Observations and Findings

CHN was authorized under NRC License Number 13-06009-01 to possess and use diagnostic and therapeutic radiopharmaceuticals as well as various sealed sources and devices for brachytherapy. The licensee had five licensed facilities located in Indianapolis, Indiana: Community Hospital East, Community Hospital North, Community Hospital South, Community Regional Cancer Center South, and Community Cancer Center North. 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 to provide oversight of licensed activities.

The last routine inspection of the licensee was in January of 2020 and no violations were identified. Prior to that, a routine inspection was conducted in April of 2018 and no violations were identified.

2 Dose to an Embryo and I-131 Program

2.1 Inspection Scope

From November 15, 2021, through July 14, 2022, the inspector reviewed the circumstances surrounding an event involving a dose to an embryo that was reported on November 5, 2021, and the licensed activities associated with the licensee's use of I-131 at the Community Hospital South location. The inspector toured the facility, observed licensed activities and demonstrations of licensed activities, conducted interviews, and reviewed selected records. Selected records included: dose calibrator calibrations, dose estimates, event chronology, patient release determinations and instructions, pregnancy test results, policies and procedures, training, quarterly audits, written directives, and written notifications.

2.2 Observations and Findings

CHN's Community Hospital South facility typically treated 3-4 patients with I-131 per quarter. CHN had a policy in place that required a negative pregnancy test within 0-7 days prior to the administration of I-131 requiring a written directive. Additionally, CHN provided written instructions to patients receiving I-131 requiring a written directive as required by 10 CFR 35.75. The instructions were specific to the activity range being

administered and the condition being treated and included elements from Regulatory Guide 8.39, Release of Patients Administered Radioactive Material. CHN used a virtual medical translation service when patients did not speak English. The service used a tablet to stream a live translator. The service provided translation for more than a dozen languages.

Event Overview

Prior to September 30, 2021, an individual was counselled and screened by a referring physician and it was determined that the individual was a candidate for I-131 therapy. The counselling included discussion on the fact that a pregnancy test would be required to confirm the individual was not pregnant. The individual was referred to an Authorized User (AU) at CHN's Community Hospital South for the therapy. The AU reviewed the case and scheduled the administration for September 30, 2021. A pregnancy test was performed on September 23, 2021; the results indicated that the patient was not pregnant.

On September 30, 2021, a copy of written instructions was provided to the patient. A nuclear medicine technologist counselled the individual on the written instructions using the virtual medical translation service. The patient signed the instructions and a 148 mCi dose of I-131 sodium iodine was administered without complication.

On November 2, 2021, the patient contacted their endocrinologist because their menstrual cycle was late. The endocrinologist ordered a pregnancy test and positive results were received on November 4, 2021. The endocrinologist informed the AU the same day. The patient believed the date of conception was likely September 29, 2021, or October 10, 2021. The patient was referred to an obstetrics and gynecology physician (OB-GYN). On November 15, the OB-GYN estimated the conception date to be October 7, 2021. The referring physician determined that the patient should not be informed of the exposure to the embryo based on the harm that it could cause the patient. However, when the patient was referred to the OB-GYN, the hospital's patient care team determined the patient should be informed of the exposure to the embryo and the referring physician informed the patient of the dose to the embryo. The physician determined there was likely no impact to the embryo since spontaneous abortion did not occur.

On November 4, 2021, the RSO performed two calculations for the embryo exposure. The first calculation was based on a conception date of September 29, 2021, which estimated a dose of 394.3 mSv (39.43 rem) to the embryo. The second calculation was based on a conception date of October 10 and estimated a dose of 1.7 mSv (0.17 rem) to the embryo. The RSO reported the embryo exposure to the NRC in accordance with 10 CFR 35.3047 on November 5, 2021, because of the possibility of the dose to the embryo being greater than 50 mSv (5 rem). The RSO provided revised calculations based on a conception date of October 7, 2021, which resulted in an estimated dose of 1.7 mSv (0.17 rem) to the embryo.

EN Number 55563 and NMED number 210467 were assigned. The licensee submitted a written report on November 11, 2021, and later provided a supplemental report on November 17, 2021. The inspector determined that the licensee's notification and the written report met the content and timeliness requirements of 10 CFR 30.3047. NMED 210467 is closed.

The inspector independently reviewed the licensee's dose estimates for the dose to the embryo. The inspector agreed that the licensee's approach was appropriate based on the available information.

Corrective and Preventative Actions

The licensee reviewed their I-131 program and implemented preventative measures to reduce the risk of recurrence of a similar type of embryo exposure. The licensee focused on three areas:

1) The licensee's policy required a negative pregnancy test 0-7 days prior to the administration of I-131 requiring a written directive. To reduce the risk of false negative test results, the licensee reduced the time frame in their policy so that a negative pregnancy test is required 0-48 hours prior to the administration I-131 requiring a written directive.
2) The licensee provided written instructions to patients prior to administrations I-131 requiring a written directive. While the previous instructions met the NRC requirements, the licensee added clarifying language to explicitly dissuade intercourse for 72 hours and advised patients to prevent pregnancy for 6 months.
3) The licensee changed their workflow such that patients are counselled on the written instructions a couple of days prior to time of treatment and immediately before the treatment.

2.3 Conclusions

The licensee reported the possible dose to an embryo based on available information as required by 10 CFR 35.3047. It was later determined that the dose to the embryo was below the reportable limit of 50 mSv (5 rem) dose equivalent. However, the licensee continued to develop and implement actions to prevent recurrence of similar types of events in the future. Within the scope of this inspection, the NRC did not identify any violations of NRC requirements.

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: 30650
Calibration Expiration: June 28, 2022

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on November 15, 2021. Upon completion of in-office review, a virtual exit meeting was held on July 14, 2022, with the licensee. On both occasions, the licensee committed to implementing actions to prevent recurrence of similar types of events.

LIST OF PERSONNEL CONTACTED

^# Erin Bell, MHP, RSO
^ Derek Blaakman, Lead Nuclear Medicine Technologist
^ James Blahunka, MD
^ Melissa Evanson, Patient Safety & Risk Manager
^ Nicole Goddard, Vice President of Operations at Community Hospital South
^# Kate Myers, Director of Imaging at Community Hospital South
^ Brett Shipley, Director of Quality at Community Hospital South
# Beth Tharp, SVP, President Hospital Services

^ Attended entrance meeting on November 15, 2021
# Attended virtual exit meeting on July 14, 2022

INSPECTION PROCEDURES USED

87103: Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
87131: Nuclear Medicine Programs, Written Directive Required

LIST OF ACRONYMS AND ABBREVIATIONS USED

AU	Authorized User
CHN	Community Health Network, Inc.
I-131	Iodine-131
mCi	millicurie
mSv	millisievert
NRC	U.S. Nuclear Regulatory Commission
OB-GYN	obstetrics and gynecology physician
RSO	Radiation Safety Officer
10 CFR	Title 10 of the *Code of Federal Regulations*