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

March 18, 2024

EN 56633
NMED No. 230304 (Closed)
Rob Schlicht
Vice President of Professional Services
North Kansas City Hospital
2800 Clay Edwards Dr.
North Kansas City, MO 64116

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03013966/2023002(DRSS) – NORTH KANSAS CITY HOSPITAL

Dear Rob Schlicht:

On August 17, 2023, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at North Kansas City Hospital located in North Kansas City, Missouri, with continued in-office review through March 6, 2024. 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 May 10, 2023. The event was reported to the NRC on July 21, 2023. The in-office review included a review of the estimated dose to the embryo submitted by the licensee and the NRC consultant physicist. Debbie Piskura and Zahid Sulaiman of my staff conducted a virtual exit meeting with you and your staff on March 6, 2024, 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 "Agency Rules of Practice and Procedure," in Title 10 of the *Code of Federal Regulations* (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 Zahid Sulaiman of my staff if you have any questions regarding this inspection. Zahid can be reached at 630-829-9752.

Sincerely,

Signed by Edwards, Rhex
on 03/18/24

Rhex A. Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

Docket No. 030-13966
License No. 24-18628-01

Enclosure: NRC Inspection Report 03013966/2023002(DRSS)

cc w/encl: Karen Hopping, R.T., Radiation Safety Officer
State of Missouri

Letter to R. Schlicht from R. Edwards dated, March 18, 2024.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03013966/2023002(DRSS) – NORTH KANSAS CITY HOSPITAL

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OFFICE	RIII DRSS		RIII DRSS		RIII DRSS			
NAME	ZSulaiman:brt		DPiskura		REdwards			
DATE	3/8/24		3/13/24		3/18/24			

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-13966
License No.	24-18628-01
Report No.	03013966/2023002(DRSS)
EN No.	56633
NMED No.	230304
Licensee:	North Kansas City Hospital
Facility:	2800 Clay Edwards Dr. North Kansas City, MO 64116
Inspection Dates:	Onsite August 17, 2023 In-office review through March 6, 2024
Exit Meeting Date:	March 6, 2024
Inspectors:	Deborah Piskura, Senior Health Physicist Zahid Sulaiman, Health Physicist
Approved By:	Rhex A. Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

Enclosure

EXECUTIVE SUMMARY

North Kansas City Hospital
NRC Inspection Report 03013966/2023002(DRSS)

This was an announced reactive inspection at North Kansas City Hospital (NKCH). The licensee was a large medical institution located in North Kansas City, Missouri. The U.S. Nuclear Regulatory Commission (NRC) License Number 24-18628-01 authorized the licensee 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 July 21, 2023, and the licensed activities associated with the use of I-131 at NKCH. 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 May 10, 2023. Specifically, a patient received approximately 125 millicuries (mCi) of I-131 sodium iodide and subsequently discovered that they were pregnant. The pregnancy was reported to the licensee on July 21, 2023. At the time of the inspection and the licensee's telephone notification, the conception date of the embryo was unknown but presumed to be approximately 4 days before the administration. The licensee estimated a fetal whole-body dose of 310.8 mSv (31.08 rem). The NRC contracted the services of an expert consultant physicist to assist in performing a dose estimate with respect to an unintended dose to an embryo/fetus involving administration of 125 mCi of iodine-131. The NRC consultant physicist estimated a fetal whole-body dose of 333.0 mSv (33.3 rem) to the embryo, which was within 7% of the licensee's estimated fetal whole-body dose. The licensee submitted a written report to the NRC on August 3, 2023.

The licensee implemented preventative measures to reduce the risk of recurrence of a similar type of embryo exposure. On February 8, 2024, the licensee notified the NRC that the patient gave birth with no issue noted. 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 reviewing the use of I-131 as permitted by Title 10 of the *Code of Federal Regulations* (CFR) 35.300 as unsealed byproduct material for which a written directive is required, and the circumstances surrounding a dose to an embryo/fetus that occurred at North Kansas City Hospital (NKCH).

The inspectors 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

The licensee was authorized under NRC License Number 24-18628-01 to possess and use diagnostic and therapeutic radiopharmaceuticals. The licensee had two locations of use at the NKCH facility. The licensee had a full time Radiation Safety Officer (RSO) that provided radiation safety support and oversight.

The last routine inspection of the licensee was on January 18, 2023, and two SLIV violations were identified. Prior to that, a routine inspection was conducted on May 21, 2019, and no violations were identified.

2 Dose to an Embryo/Fetus and I-131 Program

2.1 Inspection Scope

From August 17, 2023, through March 6, 2024, the inspectors reviewed the circumstances surrounding an event involving a dose to an embryo/fetus that was reported on July 21, 2023, and the licensed activities associated with the licensee's use of I-131 at the NKCH location. The inspectors toured the facility, observed licensed activities and demonstrations of licensed activities, conducted interviews, and reviewed selected records. The record review included: written directives, pregnancy test results, dose calibrator calibrations, dose estimates, event chronology, radiopharmaceutical therapy patient interview questionnaire, patient's room exposures survey report, nursing log sheet, radiation safety instruction for in-house therapy with I-131, patient release determinations and instructions, policies and procedures, training, quarterly audits, post dismissal room wipe test and survey results, written notifications, and the licensee's 15-day written report. The NRC contracted the services of an expert consultant physicist to assist in performing a dose estimate with respect to the unintended dose to the embryo/fetus.

2.2 Observations and Findings

NKCH typically treated 4-6 patients with I-131 per quarter. The licensee had a policy in place that required a negative pregnancy test within 72 hours prior to the administration of I-131 requiring a written directive. Additionally, NKCH 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.

Event Overview

On April 10, 2023, the patient was screened by a referring physician (endocrinologist), and it was determined that the individual was a candidate for I-131 therapy. The patient was referred to an Authorized User (AU) at NKCH for the I-131 therapy. On April 19, 2023, the licensee received an order from the referring physician for Nuclear Medicine Thyrogen Carcinoma therapy including two injections of Thyrotropin alfa and a dose of 125.74 mCi of I-131. The licensee conducted a telephone interview of the patient on April 19, 2023. The telephone interview included a discussion of pregnancy status, pregnancy testing, and outpatient administration. Through the interview, the licensee determined that the patient could not meet the conditions for outpatient administration and would be hospitalized after the administration of I-131. The licensee discussed that a pregnancy test would be required to confirm the individual was not pregnant prior to administration. The AU reviewed the case and scheduled the administration of I-131 on May 10, 2023. On May 8, 2023, a copy of written instructions was provided to the patient and a nuclear medicine technologist (NMT) counselled the individual on the written instructions. A pregnancy test (blood serum HCG) was performed on May 8, 2023; the results indicated that the patient was not pregnant. Therefore, the patient received the first injection of Thyrotropin alfa on May 8, 2023, and the second injection of Thyrotropin alfa on May 9, 2023.

On May 10, 2023, before the administration of I-131, the NMT briefed the patient about the I-131 therapy process, hospitalization after administration of I-131, and post discharge instructions. The AU went over the I-131 administration process, received patient consent, and confirmed their understanding of the process. The AU administered 125.74 mCi of I-131 (capsule form) to the patient. The patient was hospitalized after the administration of I-131 and was discharged on May 12, 2023, with discharge instructions.

On June 29, 2023, the patient went to the NKCH emergency room where the hospital staff performed an ultrasound study and estimated that the patient was 8 weeks pregnant at that time, with an estimated conception date to be around May 6, 2023.

On July 21, 2023, the RSO and the hospital were notified by the patient's endocrinologist (referring physician) that the patient was pregnant with an estimated fetal age of 12-13 weeks, post I-131 therapy administration. The hospital presumed that the patient could have been pregnant at the time of administration or had conceived shortly after the treatment. The RSO reported the embryo/fetus exposure to the NRC in accordance with 10 CFR 35.3047 on July 21, 2023, because of the possibility of the dose to the embryo being greater than 50 mSv (5 rem). The authorized user, patient, and referring physician were notified of the unintended dose to the embryo/fetus. The licensee's consulting physicist calculated and estimated a fetal whole-body dose of 310.8 mSv (31.08 rem) to the embryo.

EN Number 56633 and NMED number 230304 were assigned. The licensee submitted a 15-day written report on August 3, 2023. The inspectors determined that the licensee's notification and the written report met the content and timeliness requirements of 10 CFR 30.3047. NMED 230304 is closed.

The independent NRC consultant physicist performed a dose estimate with respect to the unintended dose to an embryo/fetus involving administration 125.74 mCi of iodine-131. The physicist estimated a fetal whole-body dose of 333.0 mSv (33.3 rem) to the embryo. The inspectors agreed with the NRC consultant physicist estimated dose which was within 7% of the licensee estimated dose and reasonably within the range of the licensee's estimate.

On February 8, 2024, the licensee notified the NRC that the patient gave birth with no issues noted.

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) Review and update patient education materials, including pre-procedure and post-procedure.
2) Review of applicable policies and procedures will be conducted and changes will be implemented as indicated. The review will include required birth control measures for patients of child-bearing age and eligibility.
3) Re-education and competency validation for all staff involved in the care of the patients undergoing these therapies, including all policy and procedure updates.

2.3 Conclusions

The licensee reported the possible dose to an embryo based on available information as required by 10 CFR 35.3047. The licensee reviewed and updated policies and procedures and implemented 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.

4 Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on August 17,2023. Upon completion of in-office review, a virtual exit meeting was held on March 6, 2024, with the licensee. On both occasions, the licensee committed to implementing actions to prevent recurrence of similar types of events.

LIST OF PERSONNEL CONTACTED

^# Karen Hopping, R.T., RSO
^# Kerri Jenkins, COO
^ Kate Brennan, Nuclear Medicine Technologist
^ John Underwood, Radiologist, Authorized User
^# Rob Schlicht, Vice President of Professional Services

^# Darla Easley, Vice President of Quality Improvement
^ Jillian Knudsen, Director of Quality
^# Ashlyn Hull, Director of Radiology
^ Dawn Wheelhouse, Senior Director, Nursing
^ Connie Green, Director of Nursing
^ Aimee Aukshun, Quality Department, PI

^ Attended entrance meeting on August 17, 2023
# Attended virtual exit meeting on March 6, 2024

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
NKCH North Kansas City Hospital
NMT Nuclear Medicine Technologist
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*