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

July 27, 2023

Karen Hopping, R.T., RSO
Radiology Operations Supervisor
North Kansas City Hospital
2800 Clay Edwards Dr.
North Kansas City, MO 64116

SUBJECT: NORTH KANSAS CITY HOSPITAL - NRC INSPECTION REPORT NO. 03013966/2023001(DRSS) AND NOTICE OF VIOLATION

Dear Karen Hopping:

This letter refers to the inspection conducted on January 19, 2023, at your North Kansas City Hospital facility, with continued in-office review through July 5, 2023. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with 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. An initial debrief meeting was held onsite on January 19, 2023; a final exit meeting was held by telephone with you on July 5, 2023.

This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with 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.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

In 2013, the NRC issued Enforcement Guidance Memorandum (EGM) 13-003 to provide temporary enforcement guidance for dispositionaing inspection findings related to a licensee's implementation of calibration requirements for rubidium-82 (Rb-82) activity measurement systems in accordance with 10 CFR 35.60 and the requirement to determine the Rb-82 dosage before medical use in accordance with 10 CFR 35.63. This guidance allowed the NRC to use enforcement discretion to not issue violations for failure to comply with these requirements for Rb-82 generator systems if all of three criteria were met. If any of the three criteria were not met, then the NRC's normal enforcement process was to be used.

One of the criteria to allow the use of enforcement discretion was that all authorized users who use Rb-82 chloride and the Radiation Safety Officer for the facility must have successfully completed training specific to the manufacturer and model of generator and infusion cart being

used. Because the inspector identified during the inspection that the authorized users did not receive training when the licensee upgraded to a new model of generator, this criterion was not met, and the NRC was not able to use EGM 13-003 to use enforcement discretion to not cite the violations.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions taken and planned to meet the criteria in EGM 13-003; and (3) the date when all criteria in EGM 13-003 were met is already adequately addressed on the docket and include: the manufacturer provided training to all authorized users using Rb-82 chloride on the specific model of generator and infusion cart. Therefore, you are not required to respond to this letter unless the description herein 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 and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (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 safeguards information so that it can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Jason Draper of my staff at 630-829-9839 or via electronic mail at Jason.Draper@nrc.gov.

Thank you for your cooperation.

Sincerely,

Signed by Edwards, Rhex
on 07/27/23

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

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

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

Letter to K. Hopping from R. Edwards, dated July 27, 2023.

SUBJECT: NORTH KANSAS CITY HOSPITAL - NRC INSPECTION REPORT NO. 03013966/2023001(DRSS) AND NOTICE OF VIOLATION DATED JULY 27, 2023

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ADAMS Accession Number: ML23207A179

OFFICE	RIII-DRSS		RIII-DRSS					
NAME	JDraper		REdwards					
DATE	7/27/2023		7/27/2023					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

North Kansas City Hospital
North Kansas City, MO

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

During an NRC inspection conducted from January 19, 2023, through July 5, 2023, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.60(b) states, in part, that a licensee shall calibrate the instrumentation required to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject in accordance with nationally recognized standards or the manufacturer's instructions.

   Contrary to the above, between February 2022 and January 24, 2023, the licensee did not calibrate the instrumentation required to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, there are currently neither nationally recognized standards nor specific calibration procedures for calibrating detectors in a dynamic mode.

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

B. 10 CFR 35.63(a) requires that a licensee determine and record the activity of each dosage before medical use.

   Contrary to the above, between February 2022 and January 24, 2023, the licensee did not determine and record the activity of each dosage before medical use. Specifically, due to the 76 second half-life of Rb-82 and direct infusion into the patient, users of the generator systems are unable to measure patient dosages of Rb-82 prior to administration.

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

As corrective action, between January 21, 2023, and January 24, 2023, the manufacturer provided training to all authorized users using Rb-82 chloride on the specific model of generator and infusion cart.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to meet the criteria in Enforcement Guidance Memorandum (EGM) 13-003 and the date when all criteria in EGM 13-003 were met is already adequately addressed on the docket. However, you are required to submit a written 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, 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 to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated this 27 day of July 2023.