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

EA-22-126

April 5, 2023

Whit Sanders
Executive Director, Cancer Services
Mercy Hospital Joplin
100 Mercy Way
Joplin, MO 64804

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO. 03012728/2022001(DRSS) – MERCY HOSPITAL JOPLIN

Dear Whit Sanders:

This letter refers to the US Nuclear Regulatory Commission (NRC) inspection conducted on August 1, 2022, at your Joplin Missouri, facility with continued in-office review through January 10, 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. An exit meeting was held on January 10, 2023, with you and your staff, to discuss an apparent violation involving the failure to have an authorized user date and sign a written directive before an administration of iodine-131 (I-131) sodium iodide. Inspection Report No. 03012728/2022001(DRSS) was issued on January 26, 2023, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML23011A093. 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 February 7, 2023 (ML23058A081), you provided a response to the apparent violation that included corrective actions. In an email dated March 14, 2023 (ML23073A181), your radiation safety officer, Samuel Rhoades, provided a supplemental response.

Based on the information developed during the inspection and the information that you provided in your responses to the inspection report dated January 26, 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 have a written directive dated and signed by an authorized user before the administration of 193.14 megabecquerel (MBq) (5.22 millicurie (mCi)) of I-131 sodium iodide. The failure to have the written directive signed by a physician trained and authorized for the administration of I-131 is a significant safety concern. The untrained and unauthorized physician could prescribe an incorrect dosage on the written directive, which could result in unintended adverse effects. In this case no adverse effect occurred. Having an authorized individual sign written directives provides confidence that what is prescribed is appropriate. 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: (1) reviewed the license with staff and provided a copy to staff; (2) an authorized user for I-131 administrations reviewed the case and documented the dose was appropriately delivered; (3) provided appropriate vendors with a copy of the most recent license amendment and informed them of the names of the four doctors authorized for I-131; (4) reminded staff in pertinent departments of the doctors allowed to administer I-131; and (5) committed to update the nuclear pharmacy with any future amendments to the license and post the current license in the hot lab.

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 in Inspection Report No. 03012728/2022001(DRSS), your letter dated February 7, 2023, and email dated March 14, 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 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 04/05/23

John B. Giessner
Regional Administrator

Docket No. 030-12728
License No. 24-01090-03

Enclosure: Notice of Violation

cc w/encl: Samuel Rhoades, PhD, RSO
State of Missouri

Letter to W. Sanders from J. Giessner dated April 5, 2023.

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO. 03012728/2022001(DRSS) – MERCY HOSPITAL JOPLIN

DISTRIBUTION w/encl

RidsSecyMailCenter
OCADistribution
Daniel Dorman
Catherine Haney
David Pelton
Tania Martinez-Navedo
Juan Peralta
Carmen Rivera-Diaz
Jack Giessner
Mohammed Shuaibi
David Lew
Laura Dudes
Scott Morris
Lorraine Baer
John Lubinski
Robert Lewis
Kevin Williams
Michele Burgess
Robert Sun
Raymond McKinley
Mark Kowal
Rayo Kumano
Diana Betancourt-Roldan
Holly Harrington
Tracy Higgs
Meghan Blair
Jessie Quichocho
Robert Williams
Marc Ferdes
Shelbie Lewman
David Curtis
Tammy Bloomer
Jared Heck
Rhex Edwards
MIB Inspectors
Allan Barker
Harral Logaras
Darren Piccirillo
Viktoria Mitlyng
Prema Chandrathil
Kenneth Lambert
Sarah Bakhsh
Michelle Garza
Geoffrey Edwards
RidsOemailCenter Resource

ADAMS Accession Number: ML23075A324

☒ Publicly Available ☐ Non-Publicly Available ☒ Sensitive ☐ Non-Sensitive

OFFICE	RIII-EICS		RIII-DRSS		RIII-DRSS		OE	
NAME	KLambert:bw		REdwards		JHeck for TBloomer		JPeralta	
DATE	3/17/2023		3/21/2023		3/22/2023		3/30/2023	
OFFICE	RIII-EICS		RIII-ORA					
NAME	DBetancourt		MShuaibi for JGiessner					
DATE	4/4/2023		4/5/2023					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Mercy Hospital Joplin
Joplin, Missouri

Docket No. 030-12728
License No. 24-01090-03
EA-22-126

During a US Nuclear Regulatory Commission (NRC) inspection conducted on August 1, 2022, with continued in-office review through January 10, 2023, 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 35.40(a) states, in part, that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (µCi)).
>
> Condition 12.B. of NRC License No. 24-01090-03, Amendment 61, lists the individuals who are authorized users for medical use as indicated.
>
> Contrary to the above, on May 25, 2022, the licensee failed to have a written directive dated and signed by an authorized user before the administration of 193.14 MBq (5.22 millicurie (mCi)) of I-131 sodium iodide. Specifically, the written directive was signed by an individual who was not listed as authorized user for medical uses under 10 CFR 35.300 on NRC License No. 24-01090-03, Amendment 61, Condition 12.B. The individual was listed in Condition 12.B. of the license as authorized user for medical use under 10 CFR 35.100 and 35.200.

This is a Severity Level III violation (Enforcement Policy Section 6.3 c.5).

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 will be achieved, is already adequately addressed on the docket in Inspection Report No. 03012728/2022001(DRSS), the licensee's letter dated February 7, 2023, and the licensee's email dated March 14, 2023. 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, EA-22-126," and send it to the US Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, Suite 210, 2443 Warrenville Road, 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 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 5th day of April 2022.