UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2056 WESTINGS AVENUE, SUITE 400
NAPERVILLE, IL 60563-2657

May 27, 2025

EAF-RIII-2025-0014

Sharon Updike
Radiation Safety Officer
Saint Joseph Regional Medical Center
5215 Holy Cross Parkway
Mishawaka, Indiana 46545

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO. 03013685/2024001 (DRSS) - SAINT JOSEPH REGIONAL MEDICAL CENTER

Dear Sharon Updike:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 4, 2024, at your Mishawaka and Plymouth, Indiana, locations with continued in-office review through February 28, 2025. 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. During the inspection an apparent violation involving the failure to monitor individuals' occupational exposure from licensed and unlicensed radiation sources was identified. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you during an exit meeting on February 28, 2025. Inspection Report No. 03013685/2024001 (DRSS) was issued on March 26, 2025, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML25069A520. 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 April 17, 2025, Saint Joseph Health System provided a response to the apparent violation (ML25111A160).

Based on the information developed during the inspection and the information provided in the written response to the inspection report dated April 17, 2025, 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 monitor individuals' occupational exposure from licensed and unlicensed radiation sources, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1502(a)(1). This violation is of significant safety concern to the NRC because the failure to wear appropriate dosimetry results in unknown exposures to occupational workers, including the potential for overexposures (no known over exposures occurred). 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 $9,000 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) educated the physicians on the need to wear extremity badges during fluoroscopy procedures; (2) included in fluoroscopy procedures a “Timeout” for a badging/ring dosimetry check to verify that dosimetry is being worn; and (3) revised the policy “Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery” to include the “Timeout” to ensure that all assigned dosimeters are worn prior to the start of a procedure. Based on the above corrective actions, *Corrective Action* credit is warranted.

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 an 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. 03013685/2024001 (DRSS) and your letter dated April 17, 2025. 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 “Agency Rules of Practice and Procedure,” 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. 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).

Sincerely,

Signed by Giessner, Jack
on 05/27/25

John B. Giessner
Regional Administrator

Docket No. 030-13685
License No. 13-02650-02

Enclosure: Notice of Violation

cc (w/encl): LeAnn M. Springman, Director of PI
Program/Accreditation
Johanna Hoekstra, Director of
Diagnostic Imaging
State of Indiana

Letter to S. Updike from J. Giessner dated May 27, 2025.

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO. 03013685/2024001 (DRSS) - SAINT JOSEPH REGIONAL MEDICAL CENTER

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NOTICE OF VIOLATION

Saint Joseph Regional Medical Center
Mishawaka, Indiana

Docket No. 030-13685
License No. 13-02650-02
EAF-RIII-2025-0014

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 4, 2024, with continued in-office review through February 28, 2025, 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) 20.1502(a)(1) requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).
>
> Title 10 CFR 20.1201(a)(2)(ii) requires, in part, that the annual limit to the skin of the extremities is a shallow-dose equivalent of 50 rem (0.5 Sievert).
>
> Contrary to the above, during 2022 through 2023, the licensee failed to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and failed to require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii). Specifically, two interventional radiologists were not monitored for occupational extremity exposure to radiation from unlicensed sources under the control of the licensee.

This is a Severity Level III violation (Enforcement Policy Section 6.7.c.6)

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. 03013685/2024001 (DRSS) and the licensee's letter dated April 17, 2025. 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, (EAF-RIII-2025-0014)", 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, 2056 Westings Avenue, Naperville, IL 60563 within 30 days of the date of the letter transmitting this Notice of Violation.

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.

Enclosure

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

Dated this 27th day of May 2025.