



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
2056 WESTINGS AVENUE, SUITE 400  
NAPERVILLE, IL 60563-2657

October 23, 2024

EA-24-054

Tracy Thegze, RT(R)  
Executive Director  
Imaging and Therapeutic Oncology Services  
901 MacArthur Blvd.  
Munster, IN 46321

SUBJECT: NOTICE OF VIOLATION - NRC ROUTINE INSPECTION REPORT NO.  
030-31379/2023001 (DRSS); ST. MARY MEDICAL CENTER - HOBART

Dear Tracy Thegze:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 17, 2023, at your Hobart, Indiana medical center with continued in-office review through July 19, 2024. The purpose of the inspection was to determine whether licensed activities were being performed in accordance with NRC requirements. During the inspection three apparent violations of NRC requirements were identified. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you during a virtual exit meeting on July 18, 2024. Inspection Report No. 030-31379/2023001 (DRSS) was issued on August 7, 2024, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML24204A108. ADAMS is accessible from the NRC web site at <https://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference, providing a written response or requesting alternative dispute resolution before we made our final enforcement decision. In a letter dated September 4, 2024, (ML24250A084), you provided a written response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated September 4, 2024, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involve the failures to: (1) monitor individuals' exposure from licensed and unlicensed radiation sources as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1502(a)(1); (2) implement certain elements of your radiation protection program as required by 10 CFR 20.1101(a); and (3) provide instruction to individuals who were likely to receive in a year, an occupational dose in excess of 100 millirem as required by 10 CFR 19.12(a)(3). The root cause of these violations appears to be the failure to provide

adequate oversight of the personnel radiation exposure monitoring program. These violations are 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, these violations have been categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level (SL) III problem. The NRC Enforcement Policy can be found on the NRC's website at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9,000 is considered for a SL III problem.

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. The NRC staff determined that credit for corrective action is warranted. Corrective actions included the following: (1) performed dose reconstruction to estimate the physician's exposure from all radiation sources; (2) provided one to one instruction to the interventional radiologist physicians on the importance of consistently wearing their assigned dosimetry; (3) informed radiation workers on the importance of properly wearing dosimeters when working with x-ray producing devices or radioactive materials; (4) improved dosimetry distribution process to manage unused, unreturned, not returned on time, dual badges not returned at same times cases; (5) designated staff will manage dosimeter exchanges, facilitate participant enrollment, and report management and compliance issues to their department supervisors/managers and the radiation safety officer; (6) implemented an administrative pre-procedure timeout/check step to verify that staff are wearing their radiation dosimeters; (7) radiation dosimetry records will be reviewed on an ongoing basis for unusually high or unexpectedly low occupational exposure; (8) implemented a progressive discipline program for noncompliance with dosimetry program; and (9) modified online training system to allow all radiation workers the ability to access the online training manuals.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement actions, 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 problem 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 violations; (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. 030-31379/2023001 (DRSS) and your letter dated September 4, 2024. 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, 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 of my staff at 630-810-4373 or [diana.betancourt-roldan@nrc.gov](mailto:diana.betancourt-roldan@nrc.gov).

Sincerely,



Signed by Giessner, Jack  
on 10/23/24

John B. Giessner  
Regional Administrator

Docket No. 030-31379  
License No. 13-03459-03

Enclosure: Notice of Violation

cc w/encl: Santosh K. Kar, M.S.,  
Radiation Safety Officer  
State of Indiana

Letter to T. Thegze from J. Giessner dated October 23, 2024.

SUBJECT: NOTICE OF VIOLATION - NRC ROUTINE INSPECTION REPORT NO. 030-31379/2023001 (DRSS); ST. MARY MEDICAL CENTER - HOBART

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NAME	LSreenivas for JPeralta		RCarpenter		GEdwards for DBetancourt- Roldan		JGiessner	
DATE	9/30/2024		10/18/2024		10/22/2024		10/23/2024	

**OFFICIAL RECORD COPY**

## NOTICE OF VIOLATION

St. Mary Medical Center - Hobart  
Hobart, Indiana

Docket No. 030-31379  
License No. 13-03459-03  
EA-24-054

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 17, 2023, with continued in-Office review through July 18, 2024, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 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).

Contrary to the above, during calendar years 2021 through November 17, 2023, the licensee failed to monitor an individual's occupational exposure to radiation from licensed and unlicensed radiation sources under the licensee's control and failed to require the use of individual monitoring devices by an interventional radiologist, who was 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). Specifically, an interventional radiologist failed to consistently wear his assigned dosimetry (collar, whole body, and extremity) between 2021 and 2023 while working with licensed and unlicensed radiation sources.

- B. Title 10 CFR 20.1101(a) requires, in part, that each licensee develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20.

The licensee's policy number, RONC 3.70 "Personnel Radiation Monitoring," effective date September 5, 2013, Section 3.0, includes the licensee's procedures for reviewing the written report from the radiation monitor company. Item 3.1. states, in part, that "Any associate exceeding the ALARA I level in a quarter will be notified by the Radiation Safety Officer. Item L 3.2 states, in part, that any associate receiving at ALARA II level in a quarter will be investigated. Item 3.4 states, in part, all the ALARA cases will be presented and discussed at the Radiation Safety Committee.

Contrary to the above, between 2021 and 2023, the licensee failed to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20. Specifically, the licensee failed to monitor for unused dosimeters or unexpectedly low dosimetry results, and the licensee's policy, RONC 3.70 "Personnel Radiation Monitoring," effective date September 5, 2013, failed to include provisions regarding actions to be taken when dosimeters were returned unused or had unexpectedly low exposures.

Enclosure

- C. Title 10 CFR 19.12(a)(3) requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Contrary to the above, prior to November 17, 2023, the licensee failed to provide instruction to individuals who in the course of employment were likely to receive in a year an occupational dose in excess of 100 mrem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide instructions regarding the proper use of dosimeters to one interventional radiologist who was likely to receive in a year an occupational dose in excess of 100 mrem.

This is a Severity Level III problem (Examples 6.3 and 6.7).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-31379/2023001(DRSS) and the licensee's letter dated September 4, 2024. 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-24-054)," 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, Suite 400, Naperville, IL 60563-2657 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 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.

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

Dated this 23<sup>rd</sup> day of October 2024.