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

July 9, 2024

EA-24-011

Daniel Parod
President, Central Region
Ascension St. Vincent Hospital
2001 W. 86th St.
Indianapolis IN 46260

SUBJECT: NOTICE OF VIOLATION – NRC ROUTINE INSPECTION REPORT
NO. 03001579/2022002 (DRSS) – ASCENSION ST. VINCENT HOSPITAL

Dear Daniel Parod:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 3 through 7, 2022, at your Indianapolis, Indiana medical center with continued in-office review through March 18, 2024. 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, six 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 an exit meeting on March 18, 2024. Inspection Report No. 03001579/2022002 (DRSS) was issued on April 8, 2024, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML24081A206. 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 or by providing a written response before we made our final enforcement decision. In a letter dated May 7, 2024, 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, the NRC has determined that six 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. Violations A, B, and C in the Notice involved the failure of individuals to consistently wear their assigned personnel dosimeters for the last several years. The violations involved the failure to: (1) monitor three individuals' exposure from licensed and unlicensed radiation sources as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1502; (2) implement certain elements of the 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 radiation safety program specific to the personnel 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 in accordance with the NRC Enforcement Policy as a Severity Level III problem.

Violation D in the Notice involved the failure to control and maintain constant surveillance of a package containing licensed material that was in a controlled area and not in storage as required by 10 CFR 20.1802. The failure to control and maintain constant surveillance of radioactive materials is a significant security and safety concern that could result in the theft or loss of material and unknown exposures to members of the public (no loss of material or known exposures occurred). Therefore, this violation has been categorized in accordance with the NRC Enforcement Manual as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $9000 is considered for each Severity Level III problem or 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 for the dosimetry issue included: (1) providing in person training to the physicians on the requirement to wear dosimetry; (2) performing dose reconstruction evaluations to determine dose estimates for the physicians; (3) forming a new oversight committee to review and develop an action plan for unreturned, unused, and unexpectedly low dosimeter readings; (4) performing visual review of physicians to ensure proper wearing of dosimetry; and (5) revising the radiation safety manual to add a process for investigating unreturned, unused and unexpectedly low dosimeter readings. Corrective action for the unsecured radioactive material included: (1) upon identifying the unsecured package, it was placed in the secured locked nuclear medicine hot lab; (2) contacting the radioactive material supplier to correct the delivery location as “Nuclear Medicine Department;” and (3) providing a presentation to pharmacy staff on steps to take if a radioactive material package is delivered to the pharmacy again. Based on the corrective actions listed above, credit for *Corrective Action* is warranted.

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 and 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 also determined that two non-escalated Severity Level IV violations of NRC requirements occurred (Violations E and F). These violations were also categorized in accordance with the NRC Enforcement Policy. The violations involved the failure to calibrate instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions; and the failure to determine the activity in radiopharmaceutical dosages containing rubidium-82 before they were administered to patients for medical use, as required by 10 CFR 35.63(c). The violations are cited in the enclosed Notice because the criteria in NRC’s Enforcement Guidance Memorandum 13-003 for giving discretion to not cite the violations was not met in that the authorized users had not completed training specific to the manufacturer and model of generator and infusion cart being used. Corrective

actions included the manufacturer providing training to the authorized users on the model and generator and infusion cart being used. The violations are being cited in the Notice because they were identified by the inspector.

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. 03001579/2022002 (DRSS) and your letter dated May 7, 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 basis 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.

Sincerely,

Signed by Giessner, Jack
on 07/09/24

John B. Giessner
Regional Administrator

Docket No. 030-01579
License No. 13-00133-02

Enclosure: Notice of Violation

cc w/encl: William K. Breeden III, M.S., DABR,
Radiation Safety Officer
State of Indiana

Letter to D. Parod from J. Giessner dated July 9, 2024.

SUBJECT: NOTICE OF VIOLATION - NRC ROUTINE INSPECTION REPORT
NO. 03001579/2022002 (DRSS) - ASCENSION ST. VINCENT HOSPITAL

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NOTICE OF VIOLATION

Ascension St. Vincent Hospital
Indianapolis, Indiana

Docket No. 030-01579
License No. 13-00133-02
EA-24-011

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted October 3 through 7, 2022, at your Indianapolis, Indiana medical center with continued in-office review through March 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, between 2019 through October 7, 2022, the licensee failed to monitor individuals' 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 the interventional radiologists, who were 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, three interventional radiologists failed to consistently wear their assigned dosimetry (collar, whole body, and extremity) for several years 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, "Radiation Safety Manual" effective date January 2022, Section 3, Dosimetry includes the licensee's procedures for Personnel Monitoring Dose Review. Bullet 2. states, in part, that "Any monitored associate exceeding the ALARA LEVEL I and /or ALARA LEVEL II limits will receive appropriate written notification of such dose."

Contrary to the above, between 2019 and 2022, 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's policy, "Radiation Safety Manual" effective date January 2022, failed to include provisions regarding actions to be taken when dosimeters were returned unused or had unexpectedly low exposures.

C. Title 10 CFR 19.12(a)(3) requires 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 October 7, 2022, 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 three interventional radiologists who were likely to receive in a year an occupational dose in excess of 100 mrem.

This is a Severity Level III problem (Enforcement Policy Section 6.3.c and 6.7.c).

D. Title 10 CFR 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, controlled area means an area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and an unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on May 2, 2022, the licensee did not control and maintain constant surveillance of a package delivered to the nuclear medicine department imaging camera control room, a controlled area, containing 540 millicuries of yttrium-90 microspheres. Specifically, a member of the licensee staff left the package unattended for an unknown period in an unlocked camera control room.

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

E. Title 10 CFR 35.60(b) requires licensees to calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, from July 20, 2022, to October 5, 2022, the licensee did not calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, in July 2022 the licensee obtained a rubidium-82 radionuclide generator which had a dynamic detector as the instrumentation required by 10 CFR 35.60(a). However, there is no nationally recognized standards or manufacturer's instructions for calibration of a dynamic detector, so the licensee was unable to calibrate the instrumentation in accordance with nationally recognized standards or the manufacturer's instructions.

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

F. Title 10 CFR 35.63(c) requires that, for other than a unit dosage, the licensee must determine the activity either by (1) direct measurement of the radioactivity; (2) a combination of measurement of radioactivity and mathematical calculations; or (3) a combination of volumetric measurements and mathematical calculations, based on the measurements made by a manufacturer or preparer licensed under Section 32.72 of this chapter or equivalent Agreement State requirements.

Contrary to the above, from July 20, 2022, to October 5, 2022, the licensee did not determine the activity in radiopharmaceutical dosages containing rubidium-82 before they were administered to patients for medical use. Specifically, the licensee obtained a rubidium-82 radionuclide generator, which used a dynamic detector to determine the activity of the rubidium-82 radiopharmaceutical. This detector has no nationally recognized standards or manufacturer's instruction for calibration. Therefore, the

dynamic detector does not meet the requirements for determination of activity in a radiopharmaceutical dosage.

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

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. 03001579/2022002(DRSS), and the licensee's letter dated May 7, 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-24-011," 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, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 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.

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

Dated this 9th day of July 2024.