



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

January 3, 2024

EA-23-110
NMED No. 230096 (closed)

Annie Kalappambath, M.D.
Radiation Safety Officer
Ascension Providence Rochester Hospital
1101 W. University Dr.
Rochester, MI 48307

SUBJECT: NOTICE OF VIOLATION; NRC NON-ROUTINE INSPECTION REPORT
NO. 03002157/2023001 (DRSS) - ASCENSION PROVIDENCE ROCHESTER
HOSPITAL

Dear Dr. Annie Kalappambath:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted between March 7, 2023, and October 23, 2023, at your Rochester, Michigan facility. The purpose of the inspection was to evaluate your activities regarding the reported event involving the shipment of licensed material. An exit meeting was held on October 23, 2023, with you and your staff to discuss an apparent violation involving the failure to control and maintain constant surveillance of licensed material that was not in storage. Inspection Report No. 03002157/2023001 (DRSS) was issued on November 13, 2023, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML23306A152. 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, by providing a written response, or by providing no response if you believed that your understanding of the event and response was properly described in our inspection report before we made our final enforcement decision. In an email dated November 22, 2023, Mr. Louis Bischof indicated that no further response would be provided as he believed that Ascension Providence Rochester's understanding of the event and its response was properly described in our inspection report.

Based on the information developed during the inspection and the information in Event Notification 56395, 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 control and maintain constant surveillance of 112 millicuries of gadolinium-153 sources that were not in storage as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1802. On March 7, 2023, the sources were mistakenly shipped with a nuclear medicine camera that was to be disposed. The sources were recovered on March 10, 2023, and returned to the hospital. The root cause of the violation was the failure to verify that the sources were removed prior to shipping the camera.

The failure to control licensed material is a significant safety concern that resulted in the material being mistakenly shipped such that members of the Public could have had access to the sources and unnecessary exposure to radiation could have occurred. In this case no known 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 \$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. Immediate corrective actions included arranging to have the sources removed from the camera and transported back to the hospital. Additional corrective actions included: (1) revising procedures to ensure that future decommissioning of camera systems that contain sealed sources will be conducted by the contracted vendor; and (2) the visual verification that sources have been removed will be confirmed by both the contracted vendor and at least one staff member of the Imaging Services Department at the hospital. Based on the above corrective actions, *Corrective Action* credit is warranted.

Therefore, to encourage prompt identification 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 on the docket in Inspection Report No. 03002157/2023001 (DRSS). 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, proprietary, or security-related 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,



Shuaibi, Mohammed signing on behalf
of Giessner, Jack
on 01/03/24

John B. Giessner
Regional Administrator

Docket No. 030-02157
License No. 21-13562-01

Enclosure: Notice of Violation

cc w/encl: State of Michigan
State of Ohio

Letter to A. Kalapparambath from J. Giessner dated January 3, 2024.

SUBJECT: NOTICE OF VIOLATION; NRC NON-ROUTINE INSPECTION REPORT
NO. 03002157/2023001 (DRSS) - ASCENSION PROVIDENCE ROCHESTER
HOSPITAL

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NOTICE OF VIOLATION

Ascension Providence Rochester Hospital
Rochester, Michigan

Docket No. 030-02157
License No. 21-13562-01
EA-23-110

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted between March 7, 2023, and October 23, 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) 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.

Contrary to the above, from March 7 through March 10, 2023, the licensee failed to control and maintain constant surveillance of 28 gadolinium-153 line sources located in a nuclear medicine camera that was shipped with a contract carrier, which was an unrestricted area.

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

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. 03002157/2023001 (DRSS). 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-23-110)" 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 (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, proprietary, or security-related 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 3rd day of January 2024.

Enclosure