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

November 13, 2023

EA 23-110
EN 56395
NMED No. 230096 (closed)

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

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

Dear Dr. Annie Kalapparambath:

From March 7, 2023, through October 23, 2023, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a non-routine review of activities performed under your license. The purpose of the review was to evaluate your activities concerning a reported event regarding the improper shipment of licensed material. The enclosed inspection report presents the results of the review. The inspector discussed the findings of the review telephonically with you on October 23, 2023.

This inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions in your license. Within these areas, the inspection consisted of an examination of selected records and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation concerned the failure to maintain constant surveillance of licensed material not in storage, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20.1802. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with you at the inspection exit meeting conducted by Geoffrey Warren on October 23, 2023. As a result, it may not be necessary to conduct a pre-decisional enforcement conference in order to enable the NRC to make an enforcement decision.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) provide no further response if you believe that your understanding of the event and response is properly

described in this report and in previous correspondence. If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. **Please contact Rhex Edwards at (630) 829-9722 or Rhex.Edwards@nrc.gov within 10 days of the date of this letter of your intended response or request.** A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03002157/2023001(DRSS); EA-23-110," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. Your response should be sent to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doccollections/gen-comm/info-notices/1996/in96028.html. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a pre-decisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with the NRC's "Agency Rules of Practice and Procedure" in 10 CFR 2.390, a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Geoffrey Warren of my staff if you have any questions regarding this inspection. Geoffrey can be reached at 630-829-9742 or Geofrey.Warren@nrc.gov.

Sincerely,

Heck, Jared signing on behalf
of Curtis, David
on 11/13/23

David Curtis, Director
Division of Radiological Safety and Security

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

Enclosure:
Inspection Report No. 03002157/2023001(DRSS)

cc w/encl: State of Michigan
State of Ohio

Letter to A. Kalapparambath from David Curtis, dated November 13, 2023.

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

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DATE	11/13/23		11/13/23					

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02157
License No.	21-13562-01
Report No.	03002157/2023001(DRSS)
EA No./NMED No.	EA-23-110 / 230096
Licensee:	Ascension Providence Rochester Hospital
Facility:	1101 W. University Dr. Rochester, Michigan
Inspection Dates:	March 7, 2023 - October 23, 2023
Exit Meeting Date:	October 23, 2023
Inspector:	Geoffrey Warren, Sr. Health Physicist
Approved By:	Rhex Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

Enclosure

EXECUTIVE SUMMARY

Ascension Providence Rochester Hospital
NRC Inspection Report 03002157/2023001(DRSS)

This was a reactive inspection concerning an unintended shipment of licensed material. The licensee operates a hospital in Rochester, Michigan, which provides diagnostic and therapeutic nuclear medicine services as well as permanent implant brachytherapy.

On March 7, 2023, the licensee shipped a nuclear medicine camera containing 28 gadolinium-153 (Gd-153) sources totaling 112 millicuries under the mistaken belief that the sources had been removed. The licensee's contracted physicist identified that the shipment contained the sources the following day through the routine audit program and the licensee took immediate action to stop the shipment. The carrier secured the truck that was transporting the camera in a warehouse near Cleveland, Ohio, and the licensee arranged to have the sources removed and couriered back to the hospital on March 10. The licensee provided all required notifications and reports to the NRC in a timely manner.

The failure to maintain surveillance of the Gd-153 sources is an apparent violation of Title 10 of the *Code of Federal Regulations* 20.1802, which requires that the licensee maintain constant surveillance of licensed material that is not in storage.

The root cause of the violation was the lack of any verification of removal of the sources prior to shipping the camera. As corrective action, the licensee took immediate action to have the sources returned to the hospital as described above. In addition, the licensee revised their procedures to ensure that future decommissioning of camera systems that contain sealed sources will be conducted by the contracted vendor. The licensee further stated that visual verification of the removed sources will be confirmed by both the contracted vendor and at least one staff member of the Imaging Services Department at the hospital.

REPORT DETAILS

1 Program Overview and Inspection History

Ascension Providence Rochester Hospital, a hospital located in Rochester, Michigan, is authorized under NRC Materials License No. 21-13562-01 to use licensed material for therapeutic and diagnostic nuclear medicine and for permanent implant brachytherapy. The two most recent routine inspections of the licensee's radiation safety program, conducted in March 2018 and February 2022, did not result in any cited violations.

2 Security of Radioactive Materials

2.1 Inspection Scope

From March 7, 2023, through October 23, 2023, the inspector interviewed staff and reviewed records concerning a reported event concerning the unintended shipment of licensed material. This inspection was limited to the events surrounding and following the shipment.

2.2 Observations and Findings

On March 7, 2023, the licensee shipped a nuclear medicine camera for disposal in preparation for receiving a new camera for the department. The shipped camera contained 28 gadolinium-153 (Gd-153) sealed sources totaling 112 millicuries (mCi) at the time of the shipment. Prior to the shipment, on March 3, one technologist had removed the sources in order to verify the serial numbers of the sources but returned them into the device. A second technologist observed that the first technologist had removed the sources but had not seen that they had been replaced. On the day of the shipment, the second technologist told the service engineer, not an employee of the hospital, that the sources had been removed; the first technologist was not present that day to state otherwise. Based on this information, the service engineer prepared the camera and shipped it.

The following day, March 8, the licensee's contracted physicist arrived at the site to perform a scheduled quarterly review of the radiation safety program. As part of the review, the physicist performed an inventory of sealed sources possessed by the licensee. During the inventory, the physicist identified that the sources were missing and determined that they were still in the camera that had been shipped. The licensee contacted the carrier about the sources in the camera. As a result of this information, the carrier secured the truck, which was still in transit to the intended destination, in a cordoned-off area of a warehouse operated by the carrier near Cleveland, Ohio. The truck was held at the warehouse for two days while the licensee arranged to have the sources removed and returned. On March 10, the sources were removed from the camera by a qualified engineer, then were packaged and couriered back to the hospital for secure storage until they could be shipped for disposal. They were received at the hospital the same day.

The sources remained in the shielded position inside the camera for the entire time between when the camera was shipped and when the engineer removed the sources from the camera to be packaged and couriered. Surveys of the camera before the sources were removed confirmed that no member of the public could have received

exposure above regulatory limits during the time the camera was outside the licensee's control. As such, there was little to no risk to the public while the material was not in the licensee's control.

The licensee notified the NRC telephonically about the missing material on March 8 (EN 56395) and provided the required written report on April 6 (ML23104A184). The written report contained all required information.

The failure to maintain surveillance of the Gd-153 sources is an apparent violation of Title 10 of the Code of Federal Regulations 20.1802, which requires that the licensee maintain constant surveillance of licensed material that is not in storage. Title 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 28 gadolinium-153 line sources located in a nuclear medicine camera that was shipped with a contract carrier, which was an unrestricted area.

The root cause of the violation was the lack of any verification of removal of the sources prior to shipping the camera. As corrective action, the licensee took immediate action to have the sources returned to the hospital as described above. In addition, the licensee revised their procedures to ensure that future decommissioning of camera systems that contain sealed sources will be conducted by the contracted vendor. The licensee further stated that visual verification of the removed sources will be confirmed by both the contracted vendor and at least one staff member of the Imaging Services Department at the hospital.

2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 20.1802. The licensee took corrective action to prevent recurrence of the apparent violation.

3 Exit Meeting Summary

The NRC inspector presented inspection findings to the licensee's radiation safety officer by telephone on October 23, 2023. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

PARTIAL LIST OF PERSONNEL CONTACTED

\# Annie Kalapparambath, M.D., Radiation Safety Officer
Michelle L. Kritzman, physicist, Medical Physics Consultants

\# Attended exit meeting on October 23, 2023.

INSPECTION PROCEDURES USED

IP 87103 – Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
IP 87130 – Nuclear Medicine Programs