



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

August 28, 2024

Yuanqing Guo, M.S.
Radiation Safety Officer
Trinity Health Ann Arbor Hospital
5301 East Huron River Drive
Ann Arbor, MI 48106

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001997/2024001(DRSS) AND
NOTICE OF VIOLATION – TRINITY HEALTH-MICHIGAN / TRINITY HEALTH
ANN ARBOR HOSPITAL

Dear Yuanqing Guo:

On August 7-9, 2024, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at Trinity Health-Michigan facilities in Ann Arbor, Brighton, Chelsea, and Howell. 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. Ryan Craffey of my staff conducted a final exit meeting by telephone with you and members of hospital staff and management on August 12, 2024, to discuss the inspection findings. This letter presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy, available on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is security-related but administrative in nature. The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1). Details of the violation are available in the enclosed non-public security addendum to the inspection report (Enclosure 3). The NRC is citing the violation in the enclosed Notice because the inspector identified it.

Enclosures 1 and 3 contain Sensitive
Unclassified Non-Safeguards Information.
When separated from the Enclosures, this
transmittal letter is decontrolled.

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Y. Guo

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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 will be achieved is already adequately addressed on the docket in this letter and the enclosed inspection report. Therefore, you are not required to respond to this letter unless the description herein 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 NRC's "Agency Rules of Practice and Procedure," in 10 CFR 2.390, a copy of this letter 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>. However, because this issue involves security-related information, the Enclosures 1 and 3 and your response, if you choose to provide one, will not be made available electronically for public inspection. If you do respond, please mark the top of each page with "Security-Related Information – Withhold Under 10 CFR 2.390". To the extent possible, your 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 Ryan Craffey of my staff if you have any questions regarding this inspection. Ryan can be reached at 630-829-9655 or ryan.craffey@nrc.gov.

Sincerely,



Signed by Edwards, Rhex
on 08/28/24

Rhex Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

Docket No. 030-01997
License No. 21-00943-03

Enclosures:

1. Notice of Violation (non-public)
2. Inspection Report
3. Security Addendum (non-public)

cc w/encl: State of Michigan

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Y. Guo

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Letter to Y. Guo from R. Edwards, dated August 28, 2024.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001997/2024001(DRSS) AND
NOTICE OF VIOLATION – TRINITY HEALTH-MICHIGAN / TRINITY HEALTH
ANN ARBOR HOSPITAL

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OFFICE	RIII-DRSS		RIII-DRSS					
NAME	RCraffey:brt		REdwards					
DATE	8/27/24		8/28/24					

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**U.S. Nuclear Regulatory Commission
Region III**

Docket No. 030-01997

License No. 21-00943-03

Report No. 03001997/2024001(DRSS)

Licensee: Trinity Health-Michigan
Trinity Health Ann Arbor Hospital

Facilities Inspected: Trinity Health Ann Arbor Hospital
5301 East Huron River Drive, Ann Arbor, MI

Trinity Health Livingston
620 Byron Road, Howell, MI

Trinity Health Chelsea
775 South Main Street, Chelsea, MI

Trinity Health Michigan Heart – Brighton Campus
7575 Grand River Avenue, Brighton, MI

Inspection Dates: August 7-9, 2024

Exit Meeting Date: August 12, 2024

Inspector: Ryan Craffey, Senior Health Physicist

Approved By: Rhex Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

Enclosures 1 and 3 contain Sensitive
Unclassified Non-Safeguards Information.
When separated from those Enclosures, this
Enclosure is decontrolled.

Enclosure 2

EXECUTIVE SUMMARY

**Trinity Health-Michigan
Trinity Health Ann Arbor Hospital
NRC Inspection Report 03001997/2024001(DRSS)**

This was an unannounced routine inspection of activities involving the use of byproduct material for diagnostic and therapeutic medical uses and for irradiation of blood products. Trinity Health Ann Arbor Hospital was authorized by U.S. Nuclear Regulatory Commission (NRC) License No. 21-00943-03 to use diagnostic and therapeutic radiopharmaceuticals at eight locations in Southeast Michigan, as well as sealed sources of byproduct material for manual brachytherapy, a high dose rate remote afterloading brachytherapy unit, and a self-shielded irradiator.

Based on the results of this inspection, the NRC identified one Severity Level IV violation that was security-related but administrative in nature. Additional details regarding the violation and corrective actions since taken to address the potential for recurrence are included in the non-public security addendum to this report.

REPORT DETAILS

1 Program Overview and Inspection History

Trinity Health-Michigan / Trinity Health Ann Arbor Hospital (the licensee) was authorized by U.S. Nuclear Regulatory Commission (NRC) License No. 21-00943-03, originally issued in October 1963, to use diagnostic and therapeutic radiopharmaceuticals at eight locations in and around Ann Arbor, Michigan, including four hospitals and four cardiology clinics that continued to operate under the brand name Michigan Heart. The licensee was also authorized to use sealed sources for manual brachytherapy at the hospitals in Ann Arbor and Livonia, and for a high dose rate remote afterloading brachytherapy (HDR) unit and a self-shielded irradiator at the hospital in Ann Arbor.

At the time of the inspection, the licensee performed diagnostic administrations daily at all four hospitals using unit doses from licensed radiopharmacies. The licensee also performed diagnostic administrations (cardiac stress tests) daily at the Michigan Heart clinics in Ypsilanti and Brighton, on Tuesdays and Thursdays at the clinic in Canton, and on Mondays and Fridays at the clinic in Livonia. The licensee occasionally performed therapeutic administrations of iodine-131 (I-131) in capsule form and radium-223 (Ra-223) Xofigo unit doses at the hospital in Ann Arbor, as well as manual brachytherapy procedures (prostate seed implants) at the hospital in Livonia. The licensee used its HDR unit and self-shielded irradiator weekly.

The licensee had a full-time RSO, supported by consultants who audited each nuclear medicine department quarterly. The licensee's Radiation Safety Committee (RSC) met quarterly as well.

The NRC last performed a routine inspection of the licensee on February 3 and 4, 2022, at the hospitals in Ann Arbor and Livonia. No violations were identified during that inspection.

Prior to this, the NRC performed a routine inspection of the licensee on March 19, 2019, at the hospital in Ann Arbor and the Michigan Heart clinic in Ypsilanti. No violations were identified during that inspection, either.

2 Trinity Health Ann Arbor Hospital

2.1 Inspection Scope

The inspector visited the hospital in Chelsea to evaluate the licensee's use of radiopharmaceuticals and sealed sources at this location. The inspector observed licensed activities, interviewed licensee personnel, and reviewed a selection of records.

2.2 Observations and Findings

The inspector observed two treatments with the HDR unit, both for gynecological cancer, at the hospital's cancer center. An Authorized User (AU) and an Authorized Medical Physicist were present for the duration of both treatments, wore personnel dosimetry as assigned, and used survey instruments as required post-treatment. Both were knowledgeable of emergency response procedures, which were readily available in the

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HDR console area. The inspector also observed demonstrations of daily spot checks for the HDR unit. It and all associated equipment were in good condition, and all interlocks and indicators functioned as intended. The inspector reviewed electronic written directives and treatment documentation for a selection of recent HDR cases, as well as documentation for the last HDR source exchange and full calibration.

The inspector observed two cardiac stress tests, one bone scan, an indium-111 white blood cell tag, and a therapeutic administration of I-131 at the hospital's nuclear medicine departments. The inspector also observed the conduct of area surveys, as well as demonstrations of instrument checks. All Nuclear Medicine Technologists (NMTs) wore personnel dosimetry as assigned, utilized available ALARA practices, and were proficient at administering radiopharmaceuticals. The inspector reviewed a selection of written directives and patient-specific release calculations for recent therapeutic administrations of I-131 and a selection of written directives for recent therapeutic administrations of Ra-223 Xofigo.

The inspector observed demonstrations of irradiator use at the transfusion services department, and reviewed records of irradiator preventative maintenance and periodic sealed source leak tests. Transfusion services personnel were knowledgeable of irradiator operation and security measures.

2.3 Conclusions

The inspector had no findings at this location.

3 Trinity Health Livingston

3.1 Inspection Scope

The inspector visited the hospital in Howell to evaluate the licensee's use of radiopharmaceuticals there. The inspector observed licensed activities, interviewed licensee personnel, and reviewed a selection of records.

3.2 Observations and Findings

The inspector observed one bone scan at the hospital's nuclear medicine department, and observed demonstrations of instrument checks, receipt of packages containing radiopharmaceuticals, and handling of radioactive waste via decay-in-storage. The NMT wore personnel dosimetry as assigned, utilized available ALARA practices, and was proficient at administering radiopharmaceuticals. The inspector also reviewed the licensee's approved list of radiopharmaceutical dosages and confirmed that it had been approved by a physician currently authorized to administer radiopharmaceuticals.

3.3 Conclusions

The inspector had no findings at this location.

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4 Trinity Health Chelsea

4.1 Inspection Scope

The inspector visited the hospital in Chelsea to evaluate the licensee's use of radiopharmaceuticals there. The inspector observed licensed activities, interviewed licensee personnel, and reviewed a selection of records.

4.2 Observations and Findings

The inspector observed two cardiac stress tests at the hospital's nuclear medicine department and handling of radioactive waste via decay-in-storage. The NMT wore personnel dosimetry as assigned, utilized available ALARA practices, and was proficient at administering radiopharmaceuticals. The inspector also reviewed a selection of records for area surveys and decay-in-storage waste disposal.

4.3 Conclusions

The inspector had no findings at this location.

5 Trinity Health Michigan Heart – Brighton Campus

5.1 Inspection Scope

The inspector visited the Michigan Heart clinic in Brighton to evaluate the licensee's use of radiopharmaceuticals there. The inspector observed licensed activities, interviewed licensee personnel, and reviewed a selection of records.

5.2 Observations and Findings

The inspector observed three cardiac stress tests at the clinic and observed demonstrations of instrument checks and handling of radioactive waste via decay-in-storage. The NMT wore personnel dosimetry as assigned, utilized available ALARA practices, and was proficient at administering radiopharmaceuticals. The inspector also reviewed a selection of records for area surveys.

5.3 Conclusions

The inspector had no findings at this location.

6 Radiation Protection Program

6.1 Inspection Scope

The inspector visited the hospitals in Ann Arbor, Chelsea, and Howell, as well as the Michigan Heart clinic in Brighton to evaluate the licensee's implementation of its radiation protection program. The inspector conducted independent radiological surveys, interviewed licensee personnel, and reviewed a selection of additional records.

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6.2 Observations and Findings

The inspector performed independent and confirmatory surveys at each location visited and found no evidence of any exposures above regulatory limits to members of the public in unrestricted areas. Minor contamination was noted in the nuclear medicine department at the hospital in Chelsea; however, this was limited to cold trash in the nuclear medicine injection room and was quickly and effectively handled by the NMT via decay-in-storage.

All areas of each facility were adequately posted, and all licensed material was adequately secured against unauthorized access and removal. The licensee had calibrated, operable, and appropriate radiation detection instrumentation at each location, as well as adequate ALARA measures for the radiological conditions.

The inspector also reviewed RSC meeting minutes, periodic RSO audits of the transfusion services department, quarterly consultant audits of various nuclear medicine departments, and personnel dosimetry reports.

6.3 Conclusions

The inspector had no findings in this area.

7 Exit Meeting Summary

The inspector presented preliminary inspection findings to the RSO following the onsite inspection on August 9, 2024. The licensee did not identify any documents or processes reviewed by the inspector as proprietary nor any documentation retained as containing personally identifiable or patient information. The licensee acknowledged the findings presented.

The inspector presented final inspection findings to the RSO and to members of hospital staff and management by video teleconference on August 12, 2024

PARTIAL LIST OF PERSONNEL CONTACTED

- # Robin Arnold – Manager, Radiology Operations, Trinity Health Chelsea Hospital
Aurelian Belecciu, MS – Authorized Medical Physicist
Eva Bieniek, MD – Authorized User
- # Angela Grunn – Manager, Radiology Operations
- # Yuanqing Guo, MS, CHP – Radiation Safety Officer
- # Alonzo Lewis – President, Trinity Health Ann Arbor and Livingston Hospitals
- # Chad Lowing – Coordinator, Nuclear Medicine Clinical Operations, Trinity Health Ann Arbor Hospital
- # Ben Miles – President, Trinity Health Chelsea Hospital
- # Charlotte Murdock – Nuclear Medicine Technologist
Brian Novak – Manager, Transfusion Services
Shalini Pandya – Authorized Medical Physicist
- # Walter Sahijdak, MD – Radiation Safety Committee Chair
- # Traci Snyder – Executive Director
- # Cheryl Taylor – Chief Nursing Officer, Trinity Health Chelsea
Joel Wilkie, MD, PhD – Authorized User

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- # Michelle Wood – Coordinator, Nuclear Medicine Clinical Operations, Trinity Health Livonia Hospital
- # Derek Yaldo, MS – Authorized Medical Physicist
- # Joe Zaccaria – K9 Officer, Trinity Health Security Police

- # Attended exit meeting on August 12, 2024

INSPECTION PROCEDURES USED

- 87131 – Nuclear Medicine Programs, Written Directive Required
- 87132 – Brachytherapy Programs

- END -

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