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

June 27, 2024

Raffi Krikorian, M.D.
Radiation Safety Officer
Comprehensive Cardiovascular Consultants
715 Maple Valley Drive
Farmington, MO 63640

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036294/2023001(DRSS), INVESTIGATION REPORT NO. 3-2023-008, AND NOTICE OF VIOLATION – COMPREHENSIVE CARDIOVASCULAR CONSULTANTS

Dear Dr. Krikorian:

This letter refers to the inspection conducted on February 28, 2023, at your clinic in Farmington, Missouri, with continued in-office review through June 10, 2024. During this period of continued review, NRC's Office of Investigations also performed an investigation to determine if a nuclear medicine technologist deliberately failed to follow rules for the safe use of radiopharmaceuticals. Based on the results of the investigation, the NRC did not identify any deliberate violations of NRC requirements.

The purpose of the routine inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included an assessment of the Office of Investigations report and further evaluation of inspection findings. The enclosed inspection report presents the results of the inspection. The inspector, Ryan Craffey, discussed the preliminary inspection findings with you at the conclusion of the on-site portion of the inspection on February 28, 2023, and conducted a final exit briefing with you on June 13, 2024.

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

Based on the results of this inspection, the NRC has determined that seven Severity Level IV violations of NRC requirements occurred regarding the following: (1) inadequate area surveys; (2) unsecured byproduct material; (3) failing to notify the NRC of changes to areas where radiopharmaceuticals were used and stored; (4) using survey instruments that were not calibrated at least annually; (5) failing to determine the activity of radiopharmaceutical dosages prior to administration; (6) failing to provide recurrent hazmat training; and (7) failing to follow established procedures for the safe use of radiopharmaceuticals.

The violations were 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 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 are being cited in the enclosed Notice because the inspector identified them.

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 will be achieved is already adequately addressed on the docket in this letter and in your request dated March 15, 2024, to terminate NRC License No. 24-32459-01. 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 the NRC's "Agency Rules of Practice and Procedure," in 10 CFR 2.390, a copy of this letter, its enclosures, 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 or proprietary 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 06/27/24

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

Docket No. 030-36294
License No. 24-32459-01

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03036294/2023001(DRSS)

cc w/encl: State of Missouri

Letter to R. Krikorian from R. Edwards, dated June 27, 2024.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036294/2023001(DRSS), INVESTIGATION REPORT NO 3-2023-008, AND NOTICE OF VIOLATION – COMPREHENSIVE CARDIOVASCULAR CONSULTANTS

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DATE	6/20/24		6/27/24					

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NOTICE OF VIOLATION

Comprehensive Cardiovascular Consultants
Farmington, Missouri

License No. 24-32459-01
Docket No. 030-36294

During an NRC inspection conducted on February 28, 2023, with continued in-office review through June 10, 2024, seven 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) 20.1501(a) requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

   Title 10 CFR 20.1301(a) requires, in part, that the total effective dose to individual members of the public from the licensed operation does not exceed 0.1 rem in a year and the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour.

   Contrary to the above, as of February 28, 2023, Comprehensive Cardiovascular Consultants did not make or cause to be made surveys of its facility in Farmington, Missouri, to assure compliance with dose limits for individual members of the public in 10 CFR 20.1301(a) that were reasonable under the circumstances to evaluate the extent of radiation levels and the potential radiological hazards that could be present there. Specifically, the licensee used millicurie quantities of unsealed technetium-99m on a weekly basis, but only performed surveys of the facility once per calendar quarter, which was not a reasonable frequency for evaluating the extent of radiation levels and the potential radiological hazards that could have been present during the quarter given the short half-life (6 hours) of the byproduct material in use.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d.3).

B. Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

   Contrary to the above, on February 28, 2023, Comprehensive Cardiovascular Consultants did not secure from unauthorized removal or limit access to approximately 517 millicuries of technetium-99m, 2.50 millicuries of cobalt-57, 250 microcuries of cesium-137, and 150 microcuries of barium-133 located in its nuclear lab, a controlled area. Specifically, the window to the nuclear lab did not lock and could be opened from the outside.

This is a Severity Level IV violation (Section 6.7.d.6).

C. Title 10 CFR Part 35.14(b)(5) requires, in part, that a licensee notify the Commission no later than 30 days after adding or changing the areas of use identified in the application or on the license where byproduct material is used in accordance with either 10 CFR 35.100 or 35.200.

   Contrary to the above, as of February 28, 2023, Comprehensive Cardiovascular Consultants did not notify the Commission no later than 30 days of changes to the areas of use at its clinic in Farmington, Missouri. Specifically, several years prior to 2023, the

license modified its nuclear lab and relocated its stress lab, rooms both identified in its application dated June 17, 2013, as areas where byproduct material was used in accordance with 10 CFR 35.200. The licensee also at that time began using licensed material in a hallway adjacent to the nuclear lab which was not identified in the renewal application as an area where byproduct material was used.

This is a Severity Level IV violation (Section 6.9.d.7).

D. Title 10 CFR 35.61(a) requires that each licensee authorized for the medical use of byproduct material calibrate the survey instruments used to show compliance with 10 CFR Part 20 and 35 annually.

   Contrary to the above:

   (1) On twenty-seven occasions between August 9, 2021, and December 20, 2021, Comprehensive Cardiovascular Consultants used a survey instrument which had not been calibrated since September 27, 2017, to perform package receipt surveys and show compliance with 10 CFR 20.1906(b).

   (2) On September 13, 2021, and December 14, 2021, the licensee used a survey instrument which had not been calibrated since August 5, 2020, to perform area surveys and show compliance with 10 CFR 20.1301(a).

   (3) On October 23, 2021, the licensee used a survey instrument which had not been calibrated since September 27, 2017, to perform waste disposal surveys and show compliance with 10 CFR 35.92.

This is a Severity Level IV violation (Section 6.7.d.4).

E. Title 10 CFR 35.63(a) requires that each licensee authorized for the medical use of byproduct material determine and record the activity of each dosage before medical use.

   Contrary to the above, as of February 28, 2023, Comprehensive Cardiovascular Consultants did not determine and record the activity of radiopharmaceuticals containing millicurie quantities of technetium-99m before administering them to patients for medical use. Specifically, the licensee's nuclear medicine technologist routinely determined and recorded the activity of these radiopharmaceuticals only after administering them.

This is a Severity Level IV violation (Section 6.3.d.3).

F. Title 10 CFR 71.5(a) states, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

   Title 49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee performs any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172. The terms Hazmat Employer and Hazmat Employee are defined in 49 CFR 171.8.

Title 49 CFR 172.704(c)(2) requires, in part, that a hazmat employee receive the training required by this subpart at least once every three years.

Contrary to the above, as of February 28, 2023, Comprehensive Cardiovascular Consultants had not complied with 49 CFR 172.704(c)(2) and provided recurrent training at least once every three years to a hazmat employee that satisfied the requirements in Subpart H of 49 CFR Part 172, and the licensee otherwise met the definition of a hazmat employer in 49 CFR 171.8. Specifically, the licensee's nuclear medicine technologist had last received hazmat training on March 11, 2019.

This is a Severity Level IV violation (Section 6.3.d.4).

G. Condition 14.A of NRC Materials License No. 24-32459-01, Amendment No. 7, dated December 20, 2013, requires, in part, that the license conduct its program in accordance with the procedures contained in the application dated June 17, 2013.

In Item 10 of the application dated June 17, 2013, Comprehensive Cardiovascular Consultants states "we have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Item 12 of the licensee's General Rules for the Safe Use of Radiopharmaceuticals requires staff to use syringe shields for preparation and administration of patient doses.

Contrary to the above, as of February 28, 2023, the licensee did not conduct its program in accordance with its procedure for the safe use of byproduct material. Specifically, the licensee's nuclear medicine technologist did not routinely use a syringe shield during the preparation and administration of patient doses.

This is a Severity Level IV violation (Section 6.3.d.3).

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 this letter and in your request dated March 15, 2024, to terminate NRC License No. 24-32459-01. 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, IR 03036294/2023001(DRSS)" 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, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from 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 safeguards information so that it can be made available to the Public without redaction.

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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 27th day of June 2024.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-36294
License No.	24-32459-01
Report No.	03036294/2023001(DRSS)
Licensee:	Comprehensive Cardiovascular Consultants
Facility:	715 Maple Valley Drive Farmington, MO
Inspection Dates:	February 28, 2023 In-office review through June 10, 2024
Exit Meeting Date:	June 13, 2024
Inspector:	Ryan Craffey, Senior Health Physicist
Approved By:	Rhex Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Security

EXECUTIVE SUMMARY

Comprehensive Cardiovascular Consultants
NRC Inspection Report 03036294/2023001(DRSS)

This was an unannounced routine inspection of Comprehensive Cardiovascular Consultants, a private medical practice in Farmington, Missouri, that was authorized by NRC materials License No. 24-32459-01 to use radiopharmaceuticals for diagnostic medical use. The inspection began on February 28, 2023, at the licensee's clinic in Farmington, and continued with in-office review through June 10, 2024. During this period of continued review, NRC's Office of Investigations also performed an investigation to determine if a nuclear medicine technologist deliberately failed to follow rules for the safe use of radiopharmaceuticals. Based on the results of the investigation, the NRC did not identify any deliberate violations of NRC requirements.

Based on the results of this inspection, the NRC has determined that seven Severity Level IV violations of NRC requirements occurred regarding the following: (1) inadequate area surveys; (2) unsecured byproduct material; (3) failing to notify the NRC of changes to areas where radiopharmaceuticals were used and stored; (4) using survey instruments that were not calibrated at least annually; (5) failing to determine the activity of radiopharmaceutical dosages prior to administration; (6) failing to provide recurrent hazmat training; and (7) failing to follow established procedures for the safe use of radiopharmaceuticals.

REPORT DETAILS

1 Program Overview and Inspection History

Comprehensive Cardiovascular Consultants (the licensee) was authorized by NRC Materials License No. 24-32459-01 to use radiopharmaceuticals for diagnostic medical use at its clinic in Farmington, Missouri. At the time of the inspection, one part-time nuclear medicine technologist (NMT) performed cardiac stress tests on alternating Mondays and every Tuesday afternoon using unit doses of technetium-99m (Tc-99m) from a radiopharmacy in St. Louis. The licensee retained the services of a medical physics consulting company in Brecksville, Ohio, to audit the program quarterly.

The NRC last performed a routine inspection of the licensee on February 7 and May 20, 2019. One Severity Level IV violation of Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1801 was identified for the licensee's failure to adequately secure byproduct material in its nuclear lab.

Prior to that, the NRC performed a routine inspection of the licensee on September 17, 2013. No violations were identified during the inspection.

2 Surveys and Instrumentation

2.1 Inspection Scope

The inspector visited the licensee's facility in Farmington, reviewed a selection of records, and interviewed personnel to review the licensee's use of instrumentation in evaluating the potential radiological hazards present.

2.2 Observations and Findings

A. Frequency of Area Surveys

The inspector found that the licensee's NMT did not conduct periodic ambient radiation exposure rate surveys of the facility. A previous consultant had told the licensee that these surveys were not required and modified the licensee's survey record templates accordingly. The previous consultant did conduct area exposure rate surveys during quarterly audits, with no elevated readings noted since at least 2019. However, given that the licensee used only Tc-99m with a half-life of just six hours, these surveys would have been unable to evaluate the extent of radiation levels and the potential radiological hazards that could have been present during the quarter other than on the day of the audit when performed on a Monday which, with one exception, had been the case since 2019.

Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1501(a) requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Title 10 CFR 20.1301(a) requires, in part, that the total effective dose to individual members of the public from the licensed operation does not exceed 0.1 rem in a year and the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour.

The licensee's failure to make or cause to be made surveys to assure compliance with dose limits for individual members of the public in 10 CFR 20.1301(a) that were reasonable under the circumstances to evaluate the extent of radiation levels and the potential radiological hazards that could be present is a Severity Level IV violation of 10 CFR 20.1501(a) per example 6.3.d.3 of the NRC's Enforcement Policy.

The inspector determined the root cause of the violation to be a misunderstanding of regulatory requirements; specifically, 10 CFR 35.70(a), which requires ambient exposure rate surveys to be performed daily in areas where unsealed byproduct material requiring a written directive was prepared for use or administered. The licensee's previous consultant believed that this effectively relieved licensees whose material did not require a written directive from performing area surveys; however, such surveys are still required at a reasonable interval (though not necessarily daily) per 10 CFR 20.1501 to demonstrate compliance with the regulations in 10 CFR Part 20.

As corrective action, the licensee's new consultant retrained the NMT to conduct area surveys daily and revised the licensee's survey record template accordingly.

B. Calibration of Survey Instruments

The inspector found that, on several occasions, the licensee's previous consultant and NMT both used instruments with expired calibrations to perform surveys to show compliance with various requirements in 10 CFR Part 20 and 35. The consultant documented using a meter (s/n 188413) calibrated on August 5, 2020, to perform ambient exposure rate surveys of the licensee's facility on September 13, 2021, and December 14, 2021, to show compliance with 10 CFR 20.1301(a). The NMT documented using a different meter (s/n 192079) calibrated on September 27, 2017, to perform receipt surveys of twenty-seven packages containing unit doses of Tc-99m received between August 9, 2021, and December 20, 2021, to show compliance with 10 CFR 20.1906(b). The NMT also documented using the same meter to perform decay-in-storage waste disposal surveys on October 23, 2021, to show compliance with 10 CFR 35.92.

Title 10 CFR 35.61(a) requires that each licensee authorized for the medical use of byproduct material calibrate the survey instruments used to show compliance with 10 CFR Part 20 and 35 annually.

The licensee's failure to calibrate two instruments used to show compliance with 10 CFR 20.1301(a), 20.1906(b), and 35.92 annually is a Severity Level IV violation of 10 CFR 35.61(a) per example 6.7.d.4 of the NRC's Enforcement Policy.

The inspector determined the root cause of the violation to be a lack of attention to detail. Poor safety culture was noted as a contributing factor; specifically, the lack of personal accountability and inadequate problem identification and resolution. Despite multiple documented indicators of calibration expiration date, neither the consultant nor the NMT recognized or acted on the expired calibrations.

As corrective action, the licensee's new consultant revised the licensee's instrument calibration process to have the second survey meter (s/n 192079) recalibrated and put back into service. The other meter (s/n 188413) had already been recalibrated on December 20, 2022.

2.3 Conclusions

The inspector identified Severity Level IV violations of 10 CFR 20.1501(a) and 10 CFR 35.61(a).

3 Security of Licensed Material

3.1 Inspection Scope

The inspector visited the licensee's facility in Farmington to evaluate the licensee's measures for securing licensed material.

3.2 Observations and Findings

A. Inspection Observations

Upon arriving at the facility in Farmington (and prior to the arrival of the NMT), the inspector toured the exterior and found that the window to the licensee's nuclear lab, accessible from the back of the building, was not locked on account of a six-inch portable air conditioner exhaust vent positioned in the opening and could be opened from the outside. The inspector later learned that a case of eight radiopharmaceutical doses for the day's administrations, totaling approximately 517 millicuries (mCi) of Tc-99m at time of delivery, was present inside the nuclear lab, as were two flood sources containing 2.49 and 0.01 mCi of cobalt-57 (Co-57) each, two vial sources containing 130 and 120 microcuries (µCi) of cesium-137 (Cs-137) each, and two vial sources containing 80 and 70 µCi of barium-133 (Ba-133) each. The case and all other sources were otherwise unsecured within the lab.

Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

The licensee's failure to secure from unauthorized removal or limit access to 517 mCi of Tc-99m, 2.50 mCi of Co-57, 250 µCi of Cs-137, and 150 µCi of Ba-133 located in its nuclear lab, a controlled area, is a Severity Level IV violation of 10 CFR 20.1801 per example 6.7.d.6 of the NRC's Enforcement Policy as the unsecured material represented 568 times applicable 10 CFR Appendix C quantities.

The inspector determined that the root cause of the violation was poor safety culture; specifically, inadequate problem identification and resolution and the lack of a questioning attitude. Despite being cited for a similar failure to adequately secure licensed material in 2019 (see below), the licensee did not identify or address the security vulnerability it introduced when installing a portable air conditioner in the nuclear lab.

As corrective action, the licensee made and installed blocks in the window to prevent the sash from being opened above the air conditioning vent.

B. Follow-up on Previous Violation

The licensee was cited in 2019 for failing to secure from unauthorized removal or limit access to material in its hot lab. Specifically, the door to the nuclear lab was found to be unlocked upon arrival, with 10 mCi of Tc-99m and 1 mCi of Co-57 present inside. The licensee replaced the door lock after being unable to find a key to the original lock and discussed the requirement and expectations for security of

licensed material with staff. To follow up on this finding and the licensee's corrective action, the inspector confirmed during the on-site inspection that the doors to the nuclear lab could now lock, and the NMT maintained possession of the key.

Although a different pathway to the nuclear lab was involved, because a similar example of this violation was identified, the 2019 finding will remain open for review at a future inspection.

3.3 Conclusions

The inspector identified a Severity Level IV violation of 10 CFR 20.1801 and did not close the violation from 2019.

4 Notifications

4.1 Inspection Scope

The inspector visited the licensee's facility in Farmington, reviewed a selection of records, and interviewed personnel to determine if the licensee communicated with the NRC as required.

4.2 Observations and Findings

The inspector found that the licensee had renovated its facility in Farmington and that it no longer matched the description provided in the application dated June 17, 2013, which identified areas of use as the nuclear lab, injection room, and stress lab. The licensee had added a door to the east wall of the nuclear lab to provide passage to the injection room, which was now considered the stress lab. The former stress lab had been removed entirely to provide more space in the waiting area, and the hallway outside the nuclear lab, which had not previously been identified as an area of use, was now being used as the injection area. When asked when these changes were made, the licensee could only recall that it had been several years, and not within the last 30 days.

Title 10 CFR Part 35.14(b)(5) requires, in part, that a licensee notify the Commission no later than 30 days after adding or changing the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

The licensee's failure to notify the Commission no later than 30 days after changing the areas of use at its clinic in Farmington, Missouri, is a Severity Level IV violation of 10 CFR 35.14(b)(5) per example 6.9.d.7 of the NRC's Enforcement Policy.

The inspector determined the root cause of the violation to be a lack of understanding of regulatory requirements. The licensee was not aware of the notification requirements in 10 CFR 35.14.

As corrective action, the licensee discussed the requirements with the inspector and with its new consultant, who prepared the required notification and submitted it on April 11, 2023. The NRC incorporated the notification into Amendment No. 08 of Materials License No. 24-32459-01 dated July 6, 2023.

4.3 Conclusions

The inspector identified a Severity Level IV violation of 10 CFR 35.14(b)(5).

5 Handling and Use of Radiopharmaceuticals

5.1 Inspection Scope

The inspector visited the licensee's facility in Farmington, reviewed a selection of records, interviewed personnel, and observed the conduct of principal activities to evaluate the licensee's use of byproduct material.

5.2 Observations and Findings

A. Determining Dosages

The inspector found that since the licensee's dose calibrator had not been calibrated or in service for some time and was apparently non-functional, the NMT routinely determined the activity of each unit dose of Tc-99m radiopharmaceuticals by decay-correcting the radiopharmacy's calibrated assay as permitted by 10 CFR 35.63 (b)(2)(i). However, the NMT only determined and recorded the activity *after* administration by adjusting the calibrated dosage by the difference, in five-minute increments, between calibration and the actual time of administration.

Title 10 CFR 35.63(a) requires that each licensee authorized for the medical use of byproduct material determine and record the activity of each dosage before medical use.

The licensee's failure to determine and record the activity of radiopharmaceuticals containing Tc-99m before administering them to patients for medical use is a Severity Level IV violation of 10 CFR 35.63(a) per example 6.3.d.3 of the NRC's Enforcement Policy. No recorded dosages were found to have differed from the prescribed dosage for stress tests by more than 20 percent.

The inspector determined that the root cause of the violation was poor safety culture; specifically, poor leadership safety values and actions and inadequate problem identification and resolution, as the licensee allowed the dose calibrator to remain non-functional with inadequate compensatory measures in place. A lack of understanding of regulatory requirements, was noted as a contributing factor, as the licensee was not aware that dosages had to be determined *before* medical use.

As corrective action, the licensee's new consultant reviewed the requirement with the NMT and confirmed during a subsequent quarterly audit in April 2023 that the NMT was performing decay calculations correctly.

B. Safe Use of Radiopharmaceuticals

The inspector noted that the licensee's NMT did not use a syringe shield while handling, preparing, or administering unit doses of Tc-99m radiopharmaceuticals during the inspection. The licensee had several such shields available in the nuclear lab, but the NMT stated that they considered their technique and proficiency sufficiently quick to render a shield unnecessary and potentially counterproductive towards the practice of ALARA. However, the inspector noted that the licensee's General Rules for the Safe Use of Radiopharmaceuticals, clearly posted on a bulletin board in the nuclear lab, explicitly required the use of syringe shields while preparing and administering doses.

Condition 14.A of NRC Materials License No. 24-32459-01, Amendment No. 7, dated December 20, 2013, requires, in part, that the license conduct its program in accordance with the procedures contained in the application dated June 17, 2013.

In Item 10 of the application dated June 17, 2013, Comprehensive Cardiovascular Consultants states “we have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

10 CFR 20.1101(b) requires that licensees use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Item 12 of the licensee’s General Rules for the Safe Use of Radiopharmaceuticals requires staff to use syringe shields for preparation and administration of patient doses.

The licensee’s failure to conduct its program in accordance with its procedure for the safe use of byproduct material is a Severity Level IV violation of Condition 14.A of NRC Materials License No. 24-32459-01 per example 6.3.d.3 of the NRC’s Enforcement Policy.

The inspector determined the root cause of the violation to be a lack of understanding of procedural requirements, as the technologist was unaware that the licensee’s rules for safe use of unsealed byproduct material required the use of syringe shields.

As corrective action, the licensee’s new consultant discussed the requirement with the NMT and confirmed during a subsequent quarterly audit in April 2023 that the NMT was using syringe shields during the preparation and administration of patient doses.

5.3 Conclusions

The inspector identified Severity Level IV violations of 10 CFR 35.63(a) and Condition 14.A of NRC Materials License No. 24-32459-01.

6 Training

6.1 Inspection Scope

The inspector reviewed a selection of records, interviewed personnel, and observed the conduct of principal activities to evaluate the training and experience of licensee personnel.

6.2 Observations and Findings

The inspector found that the licensee’s NMT had not completed hazmat training since March 11, 2019. The licensee’s new consultant had identified this issue and provided training materials to the NMT during an audit on January 24, 2023. However, as of the date of the inspection, the NMT had yet to complete the training.

Title 10 CFR 71.5(a) states, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

Title 49 CFR 172.702 requires that each hazmat employer shall ensure that each hazmat employee is trained and tested, and that no hazmat employee performs any function subject to the requirements of 49 CFR Parts 171-177 unless trained, in accordance with Subpart H of 49 CFR Part 172. The terms Hazmat Employer and Hazmat Employee are defined in 49 CFR 171.8.

Title 49 CFR 172.704(c)(2) requires, in part, that a hazmat employee receive the training required by this subpart at least once every three years.

The licensee's failure to comply with 49 CFR 172.704(c)(2) and provide recurrent training at least once every three years to a hazmat employee that satisfied the requirements in Subpart H of 49 CFR Part 172 is a Severity Level IV violation per example 6.3.d.4 of NRC's Enforcement Policy.

The inspector determined the root cause of the violation to be poor safety culture; specifically, ineffective problem identification and resolution and a lack of personal accountability by the NMT.

As corrective action, the licensee's new consultant provided hazmat training to the NMT, who completed it on April 4, 2023. The inspector also confirmed that the new consultant was now tracking the NMT's completion of hazmat training during quarterly audits.

6.3 Conclusions

The inspector identified a Severity Level IV violation of 10 CFR 71.5(a).

7 Other Areas Inspected

7.1 Inspection Scope

The inspector visited the licensee's facility in Farmington, reviewed a selection of records, interviewed personnel, and observed the conduct of principal activities to evaluate additional aspects of the licensee's radiation protection program.

7.2 Observations and Findings

The inspector observed the administration of all four cardiac stress tests scheduled for the day of the inspection. The NMT was knowledgeable of administration protocols and basic radiation safety concepts including ALARA and wore personnel dosimetry as required. Independent surveys of the facility found no evidence of residual contamination or exposure in unrestricted areas above limits to the public. The NMT performed additional contamination surveys at the end of the day and similarly found no evidence of residual contamination; however, they were unable to demonstrate proficiency with the licensee's well counter; this performance concern was noted to the licensee's new consultant, who performed an evaluation and efficiency determination on the instrument and retrained the NMT on its use during a subsequent audit in April 2023.

The inspector also reviewed a selection of records during the on-site inspection and during the period of in-office review. These included quarterly consultant audits, sealed source inventories and leak tests, results of various surveys, stress test protocols approved by the licensee's authorized user, and personnel dosimetry reports, which documented unusually low doses for the NMT (all below minimally detectable since at least 2018, with the exception in 2021 when 14 millirem deep dose equivalent and 56 millirem shallow-dose-equivalent to the hands were recorded) based on workload and the lack of syringe shielding. The inspector discussed this anomalous data with the licensee's consultant, who confirmed during a subsequent audit in April 2023 that the NMT was wearing all required dosimetry.

7.3 Conclusions

The inspector identified no other violations of NRC requirements.

8 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on February 28, 2023. The licensee did not identify any documents or processes reviewed by the inspector as proprietary nor any documentation retained by the inspector as containing personally identifiable or patient information. The licensee acknowledged the findings presented and committed to address them.

The inspector presented final inspection findings to the RSO by telephone on June 13, 2024.

LIST OF PERSONNEL CONTACTED

Daniel Burgard – Nuclear Medicine Technologist
\# Raffi Krikorian, MD – Radiation Safety Officer, Authorized User
Heather Sutyak – Consultant

\# Attended exit meeting on June 13, 2024

INSPECTION PROCEDURES USED

IP 87130 – Nuclear Medicine Programs