



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

June 23, 2017

EA-17-048

Naveen Lal, M.D.  
Radiation Safety Officer  
Allen County Cardiology  
604 West Berry  
Fort Wayne, IN 46802

SUBJECT: NRC INSPECTION REPORT NO. 03035340/2016001(DNMS), NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2017-002, AND NOTICE OF VIOLATION – ALLEN COUNTY CARDIOLOGY

Dear Dr. Lal:

On October 18 and 21, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Fort Wayne, Indiana facility, with continued in-office review through November 10, 2016. During the inspection, the inspector identified four unresolved items requiring further agency review. The unresolved items were documented in the subject inspection report, dated December 8, 2016.

On November 8, 2016, the NRC Office of Investigations (OI) initiated an investigation to determine if your nuclear medicine technologist willfully failed to perform daily ambient radiation exposure rate surveys and willfully provided inaccurate and incomplete records of daily exposure rate surveys; and willfully failed to perform weekly area contamination surveys and willfully provided inaccurate and incomplete records of weekly contamination surveys. As result of the investigation, the NRC determined that your nuclear medicine technologist willfully failed to perform the actions described above and the technologist's actions resulted in violations of NRC requirements. A copy of the OI Report Factual Summary is enclosed (Enclosure 2).

Based on the results of this inspection and investigation, the NRC identified two apparent violations, which are 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 violations involved: (1) the failure to perform daily ambient exposure rate surveys and provide information to the NRC that is complete and accurate in all material respects, as required by License Condition 15.A. and Title 10 of the *Code of Federal Regulations* (CFR) Section 30.9(a); and (2) the failure to perform weekly wipe tests and provide information to the NRC that is complete and accurate in all material respects, as required by License Condition 15.A. and 10 CFR 30.9(a). Ms. Deborah Piskura of my staff discussed the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you during a telephonic exit meeting on May 22, 2017.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request

Alternative Dispute Resolution (ADR). **Please contact Mr. Aaron T. McCraw, Chief, Materials Inspection Branch, at 630-829-9650 or [aaron.mccraw@nrc.gov](mailto:aaron.mccraw@nrc.gov) within 10 days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations re: NRC Inspection Report 03035340/2016001; EA-17-048" and should include for each 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; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. 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/doc-collections/gen-comm/info-notices/1996/in96028.html>. 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 Center, with a copy mailed to the Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, it 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 PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, the PEC will be closed to public observation because information related to an OI report will be discussed and the report has not been made public. 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 lieu of a PEC, you may also request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of these issues through ADR.

Please be advised that the number and characterization of 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.

The NRC has also determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy and involved: (1) the failure to monitor the external package surfaces for radiation levels, as required by 10 CFR 20.1906(b); and (2) the failure to provide hazmat training to an employee as required by 10 CFR 71.5(a) and 49 CFR 172.704(a) and (c). The violations are cited in the enclosed Notice of Violation (Notice) (Enclosure 1). The violations are being cited in the enclosed Notice, because the NRC inspector identified them.

You are required to respond to the enclosed Notice and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in Information Notice 96-28 may also be helpful in preparing your response to the Severity Level IV violations. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be 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, your response should not include any personal privacy, propriety, or safeguards information so that it can be made publicly available without redaction.

If you have any questions regarding this matter, please contact Mr. McCraw using the information provided above.

Sincerely,

***/RA Christine Lipa Acting for/***

John B. Giessner, Director  
Division of Nuclear Materials and Safety

Docket No. 030-34530  
License No. 13-32243-01

Enclosures:

1. Notice of Violation
2. OI Report Factual Summary

cc w/encls: State of Indiana

Letter to Dr. Naveen Lal from John B. Giessner dated June 23, 2017

SUBJECT: NRC INSPECTION REPORT NO. 03035340/2016001(DNMS), NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2017-002, AND NOTICE OF VIOLATION – ALLEN COUNTY CARDIOLOGY

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**OFFICIAL RECORD COPY**

## NOTICE OF VIOLATION

Allen County Cardiology  
Fort Wayne, Indiana

License No. 13-32243-01  
Docket No. 030-34530  
EA-17-048

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 18 and 21, 2016, with continued in-office review through November 10, 2016, two violations of U.S. Nuclear Regulatory Commission (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* (CFR) Section 20.1906(b) requires each licensee to monitor the external surfaces of packages labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71.

Contrary to the above, on October 18, 2016, the licensee received two Radioactive White I labeled packages during working hours, the packages were not exempt from the monitoring requirements, and the licensee did not perform the required monitoring. Specifically, the packages received by the licensee contained unit doses of technetium-99m in liquid form.

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

- B. Title 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180 and 390-397.

Title 49 CFR 172.704(a) specifies the elements of hazmat employee training as: (1) general awareness/familiarization training, (2) function-specific training, (3) safety training; (4) security awareness training; and (5) in-depth security training, if applicable. Title 49 CFR 172.704(c)(2) requires, in part, that a hazmat employee receive initial training and recurrent training at least once every three years.

Contrary to the above, the licensee did not provide recurrent training at least once every three years, for its hazmat employees that satisfied the requirements in Subpart H to 49 CFR Part 172, and the licensee otherwise meets the definition of hazmat employer in 49 CFR 171.8. Specifically, the licensee provided hazmat employee training to a nuclear medicine technologist (a hazmat employee) on May 9, 2012, and February 26, 2016 – a period in excess of three years.

This is a Severity Level IV violation (Section 6.8).

Pursuant to the provisions of 10 CFR 2.201, Allen County Cardiology is hereby required to submit a written statement or explanation 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 of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; 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. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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.

Your response 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available 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 23<sup>rd</sup> day of June 2017.

## FACTUAL SUMMARY OF OFFICE OF INVESTIGATIONS REPORT 3-2017-002

On November 8, 2016, the U.S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a nuclear medicine technologist (NMT) at the Allen County Cardiology facility in Fort Wayne, Indiana: (1) willfully failed to perform required daily ambient radiation exposure rate surveys (daily surveys) and falsified records of the surveys, providing inaccurate or incomplete information to the NRC; and (2) willfully failed to perform required weekly area contamination surveys (weekly surveys) and falsified records of the surveys, providing inaccurate or incomplete information to the NRC. On March 9, 2017, OI completed its investigation.

On October 18, 2016, an NRC Inspector conducted an inspection of Allen County Cardiology. As part of the inspection, the inspector requested the daily and weekly survey records for the facility. The NMT provided the inspector incomplete survey records, stating that he was behind. The inspector noted that the last completed entry for the survey records was August 5, 2016. The inspector returned to the facility on October 21, 2016, to complete the inspection. At this time, the inspector was informed by the NMT and the Radiation Safety Officer that the survey records were available and up to date. They explained that the survey records were not available during the first inspection because they were misfiled. The inspector noted that the survey record entries after August 5, 2016, were written in the same ink and marked with the NMT's initials, with no corrections or revisions. The inspector further noted that the entries for October 14, 2016, and October 17, 2016, were marked with the NMT's initials even though he was out of the office on those days.

An OI investigator interviewed the NMT on January 12, 2017. When asked about the daily surveys, the NMT noted that the office procedures state that the surveys are to be performed each day. The NMT was able to identify where the book of procedures was located in the office. The NMT expressed confidence in his knowledge of regulatory requirements and duties associated with his position. The OI investigator asked whether the NMT understood that the daily surveys were NRC regulatory requirements subject to inspection and NMT responded affirmatively. The OI investigator inquired whether the NMT ever forgot to perform the daily surveys and the NMT responded: "yes, occasionally – occasionally I will forget and then I will just have to come in the next day and fill it in." The OI investigator sought to clarify this answer and asked the NMT "have you ever completely forgotten about it on a particular day and then come back and wrote it in that you did it?" The NMT answered that "there have probably been a couple of times" and that he tries to "write it in for completeness's sake." Based on the exchange with the OI investigator, it appears likely that in these instances the NMT backfills the survey results based on the results acquired the following day.

The OI investigator then asked the NMT about the timeframe (August-October 2016) when there were missing survey records. The NMT noted that during this period he likely failed to perform surveys and backfilled the results "a few or several times." The NMT explained that he "just got busy and got behind." The OI investigator questioned the NMT about the dates that he was out of the office during the month of October. The NMT admitted that he filled in the survey results for the days that he was not working by backfilling the record. The NMT further admitted to filling in the survey record for other dates during the August-October 2016 timeframe using prior recorded readings.

Based on the NMT's testimony, it appears that he failed to perform the daily surveys and record them on more than one occasion during the August-October 2016 timeframe. Further, it appears that he filled in the daily ambient survey logs with inaccurate and incomplete

information and then knowingly provided this information to the NRC. The NMT's testimony shows that he was aware that performing and recording the daily surveys are NRC requirements.

Regarding the failure to perform weekly surveys, the NMT testified that he did not have a problem fulfilling the requirement. Similar to the daily surveys, the NMT testified that he understood that the weekly surveys are NRC regulatory requirements subject to inspection. When asked whether he performed the weekly surveys pursuant to the requirements, the NMT responded "I believe so, yes." He further testified that the records of the weekly surveys provided to the inspector were accurate.

On January 17, 2017, the NMT contacted the OI investigator to further discuss his testimony. The NMT admitted that he was two or three weeks behind on the weekly surveys when the inspector requested to inspect the records on October 18, 2016. The NMT stated that he filled in the survey logs after the inspector left and presented them to the inspector as complete on October 21, 2016. The NMT understood that the surveys he marked as complete had never been performed.

Based on the evidence gathered in the OI investigation, it appears the NMT deliberately violated the requirements of License Condition 15.A, Title 10 of the *Code of Federal Regulations* (CFR) section 20.2103(a), 10 CFR 30.9(a), and the licensee's "Standard Policy and Procedure-Area Surveys and Wipe Tests."

- (1) Specifically, between August 8 and October 18, 2016, the licensee failed to conduct surveys in radiopharmaceutical elution, preparation, and administration areas, at the end of each day of use with a low range GM survey meter. In addition, the records of those surveys, which were required to be maintained by the licensee and were provided to the Commission on October 21, 2016, were not complete and accurate in all material respects in that, the nuclear medicine technologist created inaccurate records to falsely indicate that these surveys had been performed.
- (2) Specifically, between August 8 and October 13, 2016, the licensee failed to perform a weekly wipe test in radiopharmaceutical preparation, and administration areas, for removable contamination. In addition, the records of those weekly wipe tests, which were required to be maintained by the licensee and were provided to the Commission on October 21, 2016, were not complete and accurate in all material respects in that the nuclear medicine technologist created inaccurate records to falsely indicate that these weekly wipe tests had been performed.