ALLEN COUNTY
Cardiology

www.allencountycardiology.com

Louis A. Lopez, MD
Board Certified in Internal Medicine, Cardiology & Interventional Cardiology

Naveen Lal, MD
Director of Nuclear & Echocardiography Lab
Board Certified in Internal Medicine, Cardiology, Interventional Cardiology, Nuclear Cardiology & Echocardiography

July 12, 2017

Regional Administrator, Region III
U.S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532

RE: Docket No. 030-34530
Inspection Report 03035340/2016001; EA-17-048
of radioactive materials license #13-32243-01

Subject: Reply to a Notice of Violation

To Whom it May Concern:

This is in response to the referenced NRC Inspection Report, dated June 23, 2017, signed by John B. Giessner, Director, Division of Nuclear Materials and Safety. The report is regarding an NRC inspection of our facility performed from 10/18/2016 through 11/10/2016.

The above report identified 2 Apparent Violations being considered for escalated enforcement and 2 Severity Level IV violations.

We accept the violations as listed and will respond to the items by letter, rather than to request a predecisional enforcement conference.

1) NRC Statement of Apparent Violation: Failure to Perform Daily Ambient Exposure Rate Surveys and Providing Inaccurate and Incomplete Records of These Surveys.

The NRC inspection discovered that for a period of time prior to the unannounced inspection, there was failure to perform surveys of ambient radiation exposure at the end of the day in areas where unsealed radioactive material was used during that day. Further, inaccurate information was recorded concerning the surveys.

1, a. Reason for the violation:

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We have interviewed the individual responsible for performing the day of use surveys and feel the root cause of this problem was the failure to realize the safety implications of not performing them at the end of each day. This individual places a high priority on performing the diagnostic nuclear medicine procedures with the best technical quality possible for accurate diagnosis, but did not always pace a high enough priority on completing all of the requirements on a daily basis. The NRC inspection and our interview uncovered that this individual needed to place a higher emphasis on performing all of the NRC required tasks on the required frequencies at all times. A contributing factor may have been workloads that at times did not allow for completion of all work in the allotted time. The indirect causes for the above failure are felt to be inadequate inservice, failing to stress enough the importance of performing the required surveys on the day of use, the safety implications of not being able to detect potential contamination, lack of attention to detail and failing to devote the time necessary to complete all tasks.

1, b. Corrective steps that have been taken and results achieved:

The Radiation Safety Officer/Management and nuclear technologist discussed the above violation as soon as it was discovered and the surveys were again immediately reinitiated on a day of use frequency. Adequate time has been allotted for the completion of all required tasks. There is an open line of communication between the technologist and Management to ensure that sufficient time will be allotted at all times to ensure that all requirements are met. The Radiation Safety Officer now makes at least weekly audits of the records and interviews of the technologist to ensure there are no lapses in compliance. To date, results have shown this has been successful in returning to full compliance.

1, c. Corrective steps to ensure that the above violation or similar violations are not repeated:

The Radiation Safety Officer, who is also an authorized user named on the materials license and a member of Management in the practice, will continue to make frequent audits of all required nuclear medicine records and will do regular interviews and inservice with employees to ensure that problems with compliance with NRC regulations and license conditions to not reoccur. Patient procedural schedules will be regulated to ensure that adequate time is available at all times to complete the requirements.

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Additionally, audits will be completed on at least a semi-annual frequency by an outside health physics consulting service to audit the records and ensure that they are accurate and up to date.

1, d. Compliance with this item has been achieved as of this date.

2) NRC State of Apparent Violation: Failure to Perform Weekly Wipe Tests and Provide Accurate and Complete Records of the Wipe Tests

The NRC inspection discovered that for a period of time prior to the unannounced inspection, there was a failure to perform weekly wipe tests in areas where unsealed radioactive material was used and that inaccurate incomplete information was recorded concerning the wipe tests. The involved individual admitted that the information was recorded later, even though the tests had not been performed.

2, a. Reason for violation:

We have interviewed the individual responsible for the above violation and feel the root cause of the problem was that the individual did not adequately understand the importance of only recording accurate survey information. An indirect reason may be the fact that for the majority of cases, contamination or elevated exposure readings are not experienced and therefore not expected if there were no unusual events or accidents during the day. This may have affected the decision to not complete the test and to later record that they had been performed and that there was not a problem.

2, b. Corrective steps that have been taken and results achieved:

The Radiation Safety Officer/Management and nuclear technologist discussed the above violation as soon as it was discovered and the problem has not been repeated since that time. Inservice with the technologist has reinforced the need to perform all required tests and only record accurate information. The technologist has confirmed that only information concerning testing that was actually performed will be recorded.

2, c. Corrective steps to ensure that the above violation or similar violations are not repeated:

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The Radiation Safety Officer, who is also an authorized user named on the materials license and a member of Management in the practice, will continue to make frequent audits of all required nuclear medicine records and will do regular interviews, observations, and inservice with the involved employee to ensure the understanding that all required surveys and wipe tests are to be performed and only accurate information is to be recorded in the nuclear medicine records. The seriousness and potential consequences will be included in these future meetings with the technologist.

Additionally, audits will be completed on at least a semi-annual frequency by an outside health physics consulting service to audit the records to evaluate the accuracy and completeness of the records.

3. There were also 2 Severity Level IV violations listed in the June 23, 2017, NRC inspection report:

These involved:

(A) Failure to complete required monitoring on two packages received October 18, 2016

- Reason for the violation:

We have interviewed the individual responsible for performing the surveys on incoming radioactive material packages and feel the root cause of this problem was the failure to realize the safety implications of not performing the required surveys. This individual places a high priority on performing the diagnostic nuclear medicine procedures with the best technical quality possible for accurate diagnosis, but did not always place a high enough priority on completing all of the requirements on a daily basis. The NRC inspection and our interview uncovered that this individual needed to place a higher emphasis on performing all of the NRC required tasks on the required frequencies at all times. A contributing factor may have been workloads that at times did not allow for completion of all work in the allotted time. The indirect causes for the above failure are felt to be inadequate inservice, failing to stress enough the importance of performing the required surveys on the day of use, the safety implications of not being able to detect

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potential contamination, lack of attention to detail and failing to devote the time necessary to complete all tasks.

- Corrective steps that have been taken and results achieved:

The Radiation Safety Officer/Management and nuclear technologist discussed the above violation as soon as it was discovered and the surveys on all incoming radioactive materials packages were again immediately reinitiated. Adequate time has been allotted for the completion of all required tasks. There is an open line of communication between the technologist and Management to ensure that sufficient time will be allotted at all times to ensure that all requirements are met. The Radiation Safety Officer now makes at least weekly audits of the records and interviews of the technologist to ensure there are no lapses in compliance. To date, results have shown this has been successful in returning to full compliance.

- Corrective steps to ensure that the above violation or similar violations are not repeated:

The Radiation Safety Officer, who is also an authorized user named on the materials license and a member of Management in the practice, will continue to make frequent audits of all required nuclear medicine records and will do regular interviews and inservice with employees to ensure that problems with noncompliance with NRC regulations and license conditions are to not reoccur. Patient procedural schedules will be regulated to ensure that adequate time is available at all times to complete the requirements.

Additionally, audits will be completed on at least a semi-annual frequency by an outside health physics consulting service to audit the records and ensure that they are accurate and up to date.

- Compliance with this item has been achieved as of this date.

(B) Failure to Complete Required DOT HazMat Training Within The Required 3 Year Frequency

- Reason for the violation:

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We have interviewed the individual responsible for handling radioactive materials packages and determined that the reason for not completing the training requirement was the failure to realize the importance of compliance with all NRC and DOT requirements. The NRC inspection and our interview uncovered that this individual needed to place a higher emphasis on performing all of the NRC required tasks on the required frequencies at all times. A contributing factor may have been workloads that at times did not allow for completion of all work in the allotted time. The indirect causes for the above failure are felt to be inadequate inservice, failing to stress enough the importance of performing all of the NRC required tasks on the required frequencies at all times.

- Corrective steps that have been taken and results achieved:

The Radiation Safety Officer/Management and nuclear technologist discussed the above violation and the requirement has been included on a posted schedule of required tasks. The schedule is now reviewed during regular audits of the program performed by the RSO. Adequate time has been allotted for the completion of all required tasks. There is an open line of communication between the technologist and Management to ensure that sufficient time will be allotted at all times to ensure that all requirements are met. The Radiation Safety Officer now makes at least weekly audits of the records and interviews of the technologist to ensure there are no lapses in compliance. To date, results have shown this has been successful in returning to full compliance.

- Compliance with this item has been achieved as of this date.

Allen County Cardiologist, LLC management and employees understand the seriousness and importance of the above matters and are committed to ensuring that these problems do not reoccur.

Thank you.

Sincerely,

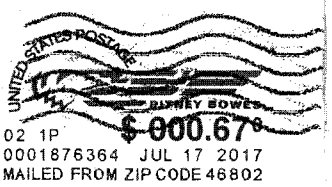
Naveen Lal

Naveen Lal, M.D., Radiation Safety Officer

ALLEN COUNTY CARDIOLOGY
604 W. Berry Street
Fort Wayne, IN 46802

RETURN SERVICE REQUESTED

FT WAYNE IN 468
18 JUL 2017



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