

August 5, 2013

Jawed H. Siddiqui, M.D.
Metro Cardiovascular Diagnostics
11115 New Halls Ferry Road
Suites 301-302
Florissant, Missouri 63033

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03037587/2013001(DNMS) –
METRO CARDIOVASCULAR DIAGNOSTIC

Dear Dr. Siddiqui:

On April 18-19, 2013, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Florissant, Missouri, with continued in-office review through July 5, 2013. 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. The in-office review included a review of additional information provided by your consultant physicist, who was not available during the onsite inspection. A final exit meeting was held between Mr. Bill Lin of my staff and you by telephone on July 8, 2013.

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 identified a number of open items for further review. The open items are described in the enclosed report. The NRC will continue to review these open items and you will be advised by separate correspondence of the results of our deliberations on these matters. No response to this letter is required at this time.

In accordance with Title 10 *Code of Federal Regulations* (CFR) Section 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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 website at

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-2-

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Should you have any questions, please contact Mr. Bill Lin of my staff at (630) 829-9829.

Sincerely,

\RA by Ann Marie Stone acting for/

Patrick L. Loudon, Acting Director
Division of Nuclear Materials Safety

Docket No. 030-37587
License No. 24-32636-01

Enclosure:
Inspection Report 03037587/2013001(DNMS)

cc w/encl: State of Missouri

J. Siddiqui

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No. 030-37587

License No. 24-32636-01

Report No. 03037587/2013001(DNMS)

Licensee: Metro Cardiovascular Diagnostics

Location Inspected: 11115 New Halls Ferry Road
Suite 301-302
Florissant, Missouri 63033

Dates: April 18-19, 2013, with continued
in-office review through July 5, 2013

Exit Meeting: July 8, 2013

Inspector: Bill C. Lin, Health Physicist

Approved by: Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

**Metro Cardiovascular Diagnostics
Florissant, Missouri
NRC Inspection Report No. 03037587/2013001(DNMS)**

This was a routine inspection conducted on April 18-19, 2013, with continued in-office review through July 5, 2013. The purpose of the inspection was to evaluate the licensee's performance and compliance with the U.S. Nuclear Regulatory Commission (NRC) regulations and license conditions. The inspector reviewed several program areas including dose calibrator linearity tests, U.S. Department of Transportation (DOT) training requirements, survey meter calibrations, efficiency tests of the well counter, waste disposal surveys, leak tests and sealed source inventories, and radiation safety program oversight.

During the inspections, the inspector identified eight open items for further review. The open items are described in the enclosed report. The NRC will continue to review these open items and advise the licensee by separate correspondence of the results of the deliberations on these matters.

Report Details

1 Program Scope and Inspection History

Metro Cardiovascular Diagnostics (licensee) is a medical private practice authorized to use licensed material permitted by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.200. The majority of licensed activities involved cardiac imaging. The nuclear medicine department was staffed with one part-time nuclear medicine technologist who performed an average of 2-4 diagnostic procedures on Tuesdays and Thursdays weekly. The licensee received and used licensed material compounded as radiopharmaceutical unit doses of labeled technetium-99m from a licensed nuclear pharmacy in the St. Louis, Missouri area. The primary authorized physician user is the owner of the medical practice and the licensee's Radiation Safety Officer (RSO). The RSO was physically present at the clinic while nuclear medicine studies were performed. The licensee had contracted with a health physics service provider to provide services for the licensee, which included all aspect of the radiation safety program as required by the NRC.

The NRC last inspected the licensee's activities on September 25, 2008, with no violations noted.

2 Survey Meter Calibration

2.1 Inspection Scope

The inspector reviewed calibration records and interviewed with the licensee's nuclear medicine technologist (NMT) and RSO.

2.2 Observations and Findings

The licensee had one survey meter, a Ludlum 14C Serial No. 248466. During the onsite inspection, the inspector observed that the licensee's survey meter had a calibration label of May 26, 2011. Subsequently, the inspector discussed the observation with the licensee's NMT. The NMT confirmed that calibration label was accurate and that the survey meter was last calibrated on May 26, 2011. This was further confirmed by the licensee's survey instrument calibration record which was dated on May 26, 2011, and was performed by the licensee's consultant physicist.

Title 10 CFR 35.61 states, a licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following repair that affects the calibration. Between May 27, 2012, and April 19, 2013, the licensee failed to calibrate its survey meter annually. The licensee's failure to annually calibrate the survey meter, a Ludlum 14C Serial No. 248466, is an open item and under further NRC review.

2.3 Conclusions

The inspector identified one open item pending further NRC review regarding the licensee's failure to annually calibrate its survey meter.

3 Waste Disposal Surveys

3.1 Inspection Scope

The inspector reviewed records of waste disposal surveys, as required by License Condition No. 14.A, and interviewed the licensee's NMT by telephone.

3.2 Observations and Findings

During a telephone conversation on April 22, 2013, the licensee's NMT confirmed with the NRC inspector that for the waste disposals that occurred on June 28, 2012, and November 11, 2012, the NMT used the Ludlum 14C Serial No. 248466 for the required waste disposal surveys. During that time, the NMT knew that the survey instrument that was used was out of calibration as of May 26, 2011. NRC Materials License 24-32636-01, License Condition 14.A, ties down licensee application dated November 6, 2006. Item 11. of licensee application states, "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meets the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92." The licensee's procedure for waste disposal states, in part, "Prior to disposal as in-house waste, monitor and record the results of monitoring each container as follows:

- 1) Use a survey instrument that is appropriate for type and energy of the radiation being measured.
- 2) Check the radiation detection survey meter for proper operation and current calibration status."

The licensee's failure to check the radiation detection survey meter for proper operation and current calibration status is an open item under further NRC review.

3.3 Conclusions

The inspector identified one open item regarding License Condition 14.A that ties down the licensee's application, dated November 6, 2006, Item 11. which requires the NMT to check the radiation detection survey meter for proper operation and current calibration status.

4 Dose Calibrator Tests

4.1 Inspection Scope

The inspector reviewed records of required dose calibrator tests, which included daily constancy tests, quarterly linearity tests, and annual accuracy tests. The inspector also reviewed the Nationally Recognized Standard and the manufacturer's instruction that were used by the licensee's consultant physicist to calibrate the dose calibrator. The review also included interviews of the licensee's consultant physicist and the licensee's NMT.

4.2 Observations and Findings

A review of the licensee's dose calibrator calibration records revealed that the last dose calibrator annual calibration was performed on May 26, 2011. For the linearity test, the licensee's record showed that the last dose calibrator linearity was performed on May 31, 2011. According to the licensee's NMT, the dose calibrator linearity test could not be performed by the NMT; the dose calibrator linearity test had to be performed by the consultant physicist or someone that was trained by the physicist. The licensee's failure to test the dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions, as required by 10 CFR 35.60(b) is an open item pending further NRC review.

4.3 Conclusions

The inspector identified one open item regarding the licensee's failure to test the dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions.

5.0 **Well Counter Efficiency Test**

5.1 Inspection Scope

The inspector reviewed the licensee's well counter efficiency test record and the interview with the licensee's consultant physicist.

5.2 Observations and Findings

Based on the review of the licensee's well counter efficiency record, the inspector determined that the well counter efficiency was last performed on May 26, 2011. Based on the licensee's procedure, which is tied down by Condition 14.A of NRC Materials License 24-32636-01, the well counter efficiency test must be performed on an annual basis. The licensee's consultant physicist also confirmed that the last time the well counter efficiency was performed was on May 26, 2011. The licensee's failure to test the well counter efficiency on an annual basis is an open item pending further NRC review.

5.3 Conclusions

The inspector identified one open item regarding the licensee's failure to perform an annual well counter efficiency calculation in accordance with license Condition 14.A of NRC Materials License 24-32636-01.

6 **Leak Tests and Sealed Source Inventories**

6.1 Inspection Scope

The inspector reviewed records of sealed source inventories and leak tests as required by 10 CFR 35.67(b)(2) and 10 CFR 35.67(g) for sealed sources used for testing of licensee instrumentation.

6.2 Observations and Findings

According to the licensee's records, leak tests were performed on the following dates: December 15, 2011, and April 23, 2013. The time period between each leak test indicates that leak tests were conducted at intervals greater than six months, as required by the regulations. The time period between December 15, 2011, and April 23, 2013, was 15 months and 15 days. Title 10 CFR 35.67(b)(2), requires a licensee in possession of a sealed source, to test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission. The failure to leak test sealed sources at intervals not to exceed 6 months is an open item under further NRC review.

According to licensee's records, physical sealed source inventories were performed on December 15, 2011, and April 23, 2013. The time period between each physical sealed source inventory indicates that physical sealed source inventories were conducted at intervals greater than semi-annually as required. The time period between December 15, 2011, and April 23, 2013, was 15 months and 15 days. Title 10 CFR 35.67(g) requires, in part, a licensee in possession of sealed sources shall conduct a semi-annual physical inventory of all such sources in its possession. The failure to conduct a semi-annual physical inventory is an open item under further NRC review.

6.3 Conclusions

The inspector identified two open items regarding 10 CFR 35.67(b)(2) for the licensee's failure to leak test sealed sources as required and 10 CFR 35.67(g) for the licensee's failure to conduct physical inventories semi-annually.

7.0 **DOT Training**

7.1 Inspection Scope

The inspector attempted to review the licensee's DOT training records.

7.2 Observations and Findings

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 DOT in 49 CFR Parts 107, 171-180, and 390-397.

Title 49 CFR 172.704(d) requires a record of current training, inclusive of the preceding three years, in accordance with this section shall be created and retained by each hazmat employer for as long as that employee is employed by that employer as a hazmat employee and for 90 days thereafter. The record shall include:

- (1) The hazmat employee's name;
- (2) The most recent training completion date of the hazmat employee's training;
- (3) A description, copy, or the location of the training materials used to meet the requirements;

- (4) The name and address of the person providing the training;
- (5) Certification that the hazmat employee has been trained and tested as required.

During the inspection, the inspector requested the latest DOT training records in accordance with DOT and NRC regulations. According to the licensee's RSO, he does not have the NMT's latest DOT training record. The licensee's NMT currently is receiving his DOT training from other cardiology clinic for which he works for when he is not at Metro Cardiovascular Diagnostics. The licensee's DOT training records are an open item pending further NRC review.

7.3 Conclusions

The inspector identified one open item regarding the licensee's DOT training records.

8 **Radiation Safety Program Oversight**

8.1 Inspection Scope

The inspector reviewed the licensee's management and oversight of the radiation safety program and the radiation protection program reviews conducted by the licensee's consultant physicist. The inspector interviewed the nuclear medicine technologist and the consultant physicist. The inspector also reviewed selected records and reports for calendar years 2011 and 2012.

8.2 Observations and Findings

The licensee's nuclear medicine studies were routinely conducted on Tuesday and Thursday of each week. The inspector observed that the NMT uses a computer program to track all aspects of the licensee's radiation protection program. The NMT's radiation safety duties and procedures included, but were not limited to, for each day of use, documenting a dose calibrator constancy test, documenting package surveys and wipe tests, documenting ambient area surveys, and documenting assays of unit doses prior to injection, on the paper record used by the NMT for recordkeeping each day licensed material is used or administered.

In reviewing the licensee documentations, the annual radiation protection program review was not performed by the licensee for 2012. The licensee had the personnel dosimetry report, and all the applicable package wipes surveys, area surveys, waste disposal surveys, and dose calibrator constancy checks; however, the annual radiation protection program review was not performed. As a result, the licensee's survey instrument that was used for all of the licensee's radiation surveys did not have an annual calibration, the quarterly linearity test on the dose calibrator was not performed, no semi-annual leak test and inventory was performed, no DOT training records were maintained, and no annual well counter efficiency was performed. If the annual review had been performed, these item could have been self-identified by the licensee and sooner than the NRC's inspection. Based on the licensee's records, the last time the licensee's survey instruments, annual and quarterly dose calibrator tests, leak tests, sealed source inventory, and well counter efficiency test were performed was between May and December of 2011. For the entire Calendar Year 2012, the licensee had been using an un-calibrated radiation survey instrument, dose calibrator, and well counter. The licensee also failed to perform the required semi-annual leak tests and inventories

on the sealed sources in their possession. This is an open item pending further review to determine the extent of the licensee's failure to implement the radiation safety program in accordance with NRC Regulatory Requirements and NRC Materials License No 24-32636-01.

8.3 Conclusions

The inspector identified one open item regarding the licensee's failure to perform a required annual radiation protection program review for Calendar Year 2012.

9 **Exit Meeting Summary**

The inspector discussed the preliminary conclusions with licensee on July 8, 2013 via telephone. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

LIST OF PERSONNEL CONTACTED

*Dr. Jawed H. Siddiqui

* Participated in the exit meeting on July 8, 2013