

ENCLOSURE 6 - INSPECTION RECORD

Region: III **Inspection Report No.** 2015-001

License No. 24-32636-01

Docket No. 030-37587

Licensee: Metro Cardiovascular Diagnostics
1115 New Halls Ferry Road
Suites 301-302
Florissant, MO

Location Inspected: 1115 New Halls Ferry Road
Suites 301-302
Florissant, MO

Licensee Contact: Jawed Siddiqui, M.D., RSO

Telephone No. 314-921-6200

Program Code: 02201 **Priority:** 5

Type of Inspection: ☐ Initial ☐ Routine ☐ Announced
 ☒ Special ☐ Unannounced

Last Inspection Date: 4/18&19/13 **Date of This Inspection:** 1/15/15, with in-office review through 1/27/15

Next Inspection Date: 1/15/20 ☒ Normal ☐ Reduced

Summary of Findings and Actions:

- ☐ No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ☐ Non-cited violations (NCVs)
- ☐ Violation(s), Form 591 issued
- ☒ Violation(s), regional letter issued
- ☒ Follow-up on previous violations

Inspector(s) Robert G. Gattone, Jr., Senior Health Physicist

/RA/

Signature

Date 02/02/2015

Inspector(s) Ed Harvey, Health Physicist

/RA/

Signature

Date 02/02/2015

Approved Arron T. McCraw, Chief, MIB

/RA/

Signature

Date: 02/05/2015

PART I - LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
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None

2. INSPECTION AND ENFORCEMENT HISTORY:

As a result of the last inspection and the associated OI investigation, one willful violation, and several non-willful violations were cited as follows:

Violation Assessed a Civil Penalty

Contrary to Condition 14 of NRC License 24-32636-01 (license), on June 28, 2012, and November 20, 2012, the licensee failed to perform the required radiation survey in accordance with License Condition 14.A of NRC materials License 24-32636-01. Specifically, the licensee's nuclear medicine technologist (NMT) willfully failed to check the radiation detection survey meter for current calibration status as required by the licensee's waste disposal procedure. The NMT used survey instrument Ludlum Model 14C, Serial No. 248466 to perform the required radiation survey for waste disposal on June 28, 2012, and November 20, 2012. At the time of the surveys, the survey instrument calibration had expired on or about May 26, 2012 (last calibrated on May 26, 2011) and was not in a current calibration status. The violation was categorized at Severity Level III and a Civil Penalty of \$3,500 was imposed.

Violations Not Assessed a Civil Penalty

- A. Title 10 of the *Code of Federal Regulations* (CFR) Section 10 CFR 35.61(a) requires, in part, that a licensee calibrate the survey instruments used to show compliance with 10 CFR Part 35 and 10 CFR Part 20 before first use, annually, and following repairs that affect the calibration.

Contrary to the above, between May 26, 2011, and April 22, 2013, the licensee failed to calibrate the survey instrument used to show compliance with 10 CFR Part 35 annually.

- B. Condition 14 of the license states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures as listed, including the application dated November 6, 2006. Item 9 of the application states, "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

10 CFR 35.60(b) requires that a licensee calibrate the instrumentation required in paragraph 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions.

The Capintec manufacturer's instruction states, in part, "The new NRC guidelines ask that you follow the manufacturer's recommendations for calibrations." The manufacturer recommends that a linearity test be performed quarterly.

A nationally recognized standard is IEC TR 61948-4—International Electrotechnical Commission Technical Report, "Nuclear Medicine Instrumentation – Routine tests – Part 4: Radionuclide Calibrators." The standard discusses linearity tests in Section 4.3 and Section 4.5 specifies a yearly frequency.

Contrary to the above, between September 26, 2011, and April 22, 2013, a dose calibrator was not calibrated in accordance with either the manufacturer's instruction or a nationally recognized standard. Specifically, the licensee failed to perform a quarterly linearity test as per the manufacturer's instruction or a yearly linearity test as per a national standard. The last linearity test was performed on May 26, 2011. A quarterly linearity test was due by September 26, 2011, and a yearly one was due by May 25, 2012.

- C. Condition 14 of the license states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. Item A. of Condition 14 is the license application dated November 6, 2006. Item 10 of the application states, "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meets the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

The licensee implemented the model procedure in Appendix K, "General Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program," of NUREG 1556, "Consolidated Guidance About Materials Licenses," Volume 9, "Program-Specific Guidance About Medical Use Licenses," which states, in part, "Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed byproduct material is prepared, administered, or stored. Calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and/or after repair."

Contrary to the above, between May 26, 2011, and April 22, 2013, the licensee failed to calculate the efficiency of the well counter used to assay wipe testing used for area surveys, as required by License Condition 14.A of NRC Materials License 24-32636-01. Specifically the licensee last performed a well counter efficiency calculation on May 26, 2011, and did not perform it again until after April 23, 2013, an interval greater than annually.

- D. 10 CFR 35.67(b)(2) requires, in part, that a licensee in possession of a sealed source shall test the source for leakage at intervals not to exceed 6 months or at other intervals approved.

Contrary to the above, the licensee failed to test its sealed sources for leakage at 6 month intervals, and no other interval was approved. Specifically, records indicated that leak tests were conducted on December 15, 2011, but no other leak tests were conducted until April 23, 2013.

- E. 10 CFR 35.67(g) requires, in part, that a licensee in possession of sealed sources shall conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, physical sealed source inventories were not performed semi-annually as required. Specifically, records indicated that a physical sealed source inventory was performed on December 15, 2011, and no other physical inventory was performed until April 23, 2013. The time period between physical inventories was greater than semi-annually.

- F. 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 Department of Transportation regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

49 CFR 172.704(d) requires, in part, that each hazmat employer must create and retain a record of current training of each hazmat employee, inclusive of the preceding three years, for as long as that employee is employed by that employer as a hazmat employee and for 90 days thereafter.

Contrary to the above, as of April 19, 2013, the licensee, a hazmat employer, failed to retain a record of current training for its hazmat employee, inclusive of the preceding three years. Specifically, the licensee only had the 2008 Department of Transportation training records for the NMT who was considered a hazmat employee as he delivered licensed material to a carrier for transport.

- G. 10 CFR 20.1101(c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, between December 2011 and April 22, 2013, the licensee failed to review the radiation protection program content and implementation, an interval that is greater than annually.

- H. 10 CFR 35.24(b) requires, in part, that a licensee appoint a radiation safety officer (RSO), who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

Contrary to the above, from approximately December 15, 2011, to April 22, 2013, the RSO failed to ensure that radiation safety activities were being performed in accordance with licensee-approved procedures and regulatory requirements. Specifically, the RSO failed to ensure that: (1) the survey meter was calibrated on an annual basis; (2) the dose calibrator was tested for linearity in accordance with either the manufacturers instruction or nationally recognized standards; (3) the well counter efficiency calibration was performed on an annual basis; (4) sealed sources were leak-tested at intervals not to exceed 6 months; (5) semi-annual physical inventories were performed; (6) Department of

Transportation training records were retained; and (7) annual radiation protection program reviews were performed timely.

This was cited as a Severity Level III problem.

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

3. INCIDENT/EVENT HISTORY:

There were no open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee is a medical private practice authorized to use licensed material permitted by 10 CFR 35.200. The majority of licensed activities involved cardiac imaging. The nuclear medicine department was staffed with one part-time NMT who performed an average of 2-4 diagnostic procedures between about 9:30am and 1:00pm on Tuesdays and Thursdays. The licensee received and used technetium-99m labeled unit dosages that were delivered by 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 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 aspects of the radiation safety program.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: 02.01, 02.02, 02.05, 02.06, 02.07

This was a special inspection to follow up on the licensee's corrective actions to prevent similar violations that resulted in escalated enforcement action as a result of the previous inspection.

Regarding the previous violation of Condition 14 of NRC Materials License No. 24-32636-01 (license), involving the licensee's NMT willful failure to check the radiation detection survey meter for current calibration status as required by the licensee's waste disposal procedure, the inspectors observed the NMT demonstrate how he had conducted decay-in-storage activities. The NMT demonstrated that he had, in part, checked the survey instrument's calibration sticker at the start of each day of use to verify that the survey instrument was calibrated as required. This violation is closed.

Regarding the previous violation of 10 CFR 35.61(a) involving licensee failure to calibrate the survey instruments used to show compliance with 10 CFR Part 35 and 10 CFR Part 20 before first use, annually, and following repairs that affect the calibration, the inspectors observed that the NMT had a survey instrument that had a calibration sticker on it stating that the instrument was calibrated by an authorized firm on 4/21/14, and the calibration sticker stated that the next calibration was due on

4/21/15. In addition, the inspectors reviewed the survey instrument's calibration certificate dated 4/21/14. This violation is closed.

Regarding the previous violation of 10 CFR 35.60(b) and Condition 14 of the license involving licensee failure to perform a quarterly linearity test as per the manufacturer's instruction or a yearly linearity test as per a national standard, the inspectors observed records of dose calibrator linearity tests that were done quarterly since the third quarter of 2013. This violation is closed.

Regarding the previous violation of Condition 14 of the license involving licensee failure to annually calculate the efficiency of the well counter used to assay wipe test samples for area surveys, the inspectors reviewed records showing that the licensee's well counter was calibrated in April 2014. This violation is closed.

Regarding the previous violation of 10 CFR 35.67(b)(2) involving licensee failure to test its sealed sources for leakage at every 6 months, the inspectors reviewed sealed source leak test records showing that applicable sealed sources were leak tested within 6 month intervals. This violation is closed.

Regarding the previous violation of 10 CFR 35.67(g) involving licensee failure to conduct semi-annual physical inventories of all sealed sources in its possession, the inspectors observed sealed source inventory records showing that the licensee conducted the inventories more often than semi-annually. This violation is closed.

Regarding the previous violation of 10 CFR 71.5(a) and 49 CFR 172.704(d) involving licensee failure to retain a record of current training for its hazmat employee, inclusive of the preceding three years, the inspectors reviewed records showing that hazmat training for its hazmat employee was conducted since the last inspection. This violation is closed.

Regarding the previous violation of 10 CFR 20.1101(c) involving licensee failures to conduct at least annually reviews of its radiation protection program content and implementation, the inspectors reviewed records of the radiation protection program audit that was conducted on 4/21/14. The inspectors noted that the audit included review of violations that were identified during the previous inspection, security of licensed material, postings, dosimetry records, accuracy and precision testing of the dose calibrator, survey instrument calibration, well counter efficiency calculation, decay-in-storage, dose calibrator linearity tests, and sealed source leak tests. This violation is closed.

Regarding the previous violation of 10 CFR 35.24(b) involving licensee failure to have its RSO ensure that radiation safety activities were being performed in accordance with licensee-approved procedures and regulatory requirements, the inspectors interviewed the licensee's RSO who stated that: (1) the licensee's consultant and the NMT can inform the RSO of radiation safety issues for prompt resolution; (2) he is now present to observe the NMT conduct licensed activities instead of asking the NMT if it was done; (3) the licensee's consultant and the NMT are now communicating with each other directly to prevent violations; and (4) the consultant conducts quarterly linearity tests and sealed source inventories. The inspectors interviewed the licensee's consultant who stated that: (1) the communication between the consultant and the licensee was improved since the last inspection; (2) the licensee was in compliance with all of the

requirements associated with the violations that were cited as a result of the previous inspection; (3) he does the annual radiation safety program audits; and (4) he does the well counter efficiency calculations. This violation is closed.

The inspectors questioned the RSO about non-payment of the imposed \$3,500 Civil Penalty. The RSO stated that he was waiting for the bill. During the exit meeting, the RSO informed the inspectors that NRC Headquarters had approved the licensee's request to pay the Civil Penalty in increments beginning in March 2015.

The inspectors observed the NMT: (1) conduct a dose calibrator constancy check prior to using the unit to measure dosages; (2) verify that the survey instrument was calibrated prior to first use of the day; (3) conduct package receipt surveys as required; and (4) administer a cardiac imaging radiopharmaceutical to a patient while using a lab coat, gloves, syringe shield, and whole body and extremity dosimeter badges.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors conducted independent ambient exposure rate surveys using an NRC owned survey instrument that was calibrated within 6 months to measure 0.05 milliroentgens per hour at the surface of a package containing licensed material that had been received from an authorized nuclear pharmacy.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

During the onsite inspection on January 15, 2015, the inspectors identified that the NMT forgot to lock applicable doors resulting in failure to secure from unauthorized removal or limit access to 300,640 microcuries of technetium-99m, 8 microcuries of cobalt-57, and 172 microcuries of cesium-137 that was stored in an unlocked, unattended hot lab that was adjacent to the imaging room. In addition, the imaging room was unlocked, unattended, and contained 545 microcuries of cobalt-57 that was being used for gamma camera calibration. The hot lab and the imaging room were controlled areas. As a result, the violation of 10 CFR 20.1801 and 20.1802 was cited at Severity Level IV. As corrective actions to restore compliance and to prevent recurrence, the inspectors observed the NMT promptly secure licensed material after the inspectors identified the violation. In addition, the licensee committed to ensure that all material will be secured whenever it is unattended by an authorized person. The licensee/RSO also committed to personally conduct periodic checks to verify that licensed material is secured as required.

5. PERSONNEL CONTACTED:

Dan Burgard, NMT
Kevin Miller, Financial Officer
#Jawed H. Siddiqui, M.D., RSO
James Hatten, Licensee's Consultant

Attended exit meeting on 1/27/15

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