INSPECTION RECORD

Region: III **Inspection Report No.** 2018001 **License No.** 24-32636-01
Docket No. 030-37587

Licensee: Metro Cardiovascular Diagnostics
11115 New Halls Ferry Rd.
Florissant, MO 63033

Locations Inspected: Same as above

Licensee Contact: Jawed Siddiqui, M.D., RSO **Telephone No**. 314-395-5827

Program Code: 02201 **Priority**: 5

Type of Inspection: ( ) Initial (X) Routine ( ) Announced
( ) Special (X) Unannounced

Last Inspection Date: 1/15/2015 with in office review thru 1/27/2015

Date of This Inspection: 07/12/2018 and 08/03/2018, with in office review thru 09/25/2018

Next Inspection Date: 01/12/2020 ( ) Normal (X) Reduced*

Justification for reducing the routine inspection interval:

Reduce next inspection based on performance and licensee's indication of financial difficulties in making payment to various services. Lack of payment for services had put the licensee close to noncompliance in several program areas.

Summary of Findings and Actions:

(X) 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
(X) Follow-up on previous violations

Inspector: Deborah Piskura, Senior Health Physicist

/RA/ Date 10/17/2018
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 10/18/2018
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
02	07/17/2018	License renewal

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection was conducted on January 15, 2015, in follow up to previous escalated enforcement taken against the licensee; the licensee's corrective actions for the previous violations were reviewed and closed during the last inspection. The last inspection identified one SL IV violation of 10 CFR Sections 20.1801 and 20.1802, for the licensee's failure to secure RAM stored in the nuclear medicine hot lab and the imaging room.

The previous inspection conducted on April 18-19, 2013, with continued in-office review through July 5, 2013, resulted in several unresolved issues (and potentially nine violations) that were referred to the Office of Investigations. The NRC concluded that one violation (SL III) involving the licensee's failure to use its survey meter in accordance with its commitments referenced by License Condition 14.A. was willful and assessed a $3,500 civil penalty. Several non-willful violations were cited as a Severity Level III problem involving the licensee's failures to: (1) calibrate the survey instrument used to show compliance with 10 CFR Part 35 annually (10 CFR 35.61(a)); (2) calibrate the dose calibrator unit in accordance with nationally recognized standards or the manufacturer's instructions (10 CFR 35.60(b) & License Condition 14.A.); (3) calculate the efficiency of the well counter used to assay wipe tests for area surveys (License Condition 14.A.); (4) test sealed sources for leakage at 6 month intervals (10 CFR 35.67(b)(2)); (5) conduct semi-annual physical inventories of all sealed sources (10 CFR 35.67(g)); (6) retain a record of hazmat training (10 CFR 71.5(a) / 49 CFR 172.704(d)); (7) review the radiation protection program content and implementation annually (10 CFR 20.1101(c)); (8) ensure (by the RSO) that radiation safety activities were being performed in accordance with licensee-approved procedures and regulatory requirements (10 CFR 35.24(b)).

3. INCIDENT/EVENT HISTORY:

No open items or events were reported by the licensee since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This was a routine, unannounced inspection of a small, independently owned cardiac clinic authorized to use byproduct material under 10 CFR 35.200 for diagnostic cardiac scans. One physician served as the authorized user and the RSO. This physician also is the owner of the practice. The clinic was open daily providing nuclear medicine cardiac studies on Tuesdays and Thursdays mornings. The licensee retained the services of a PRN nuclear medicine technologist who performed approximately 20-30 studies per month. The licensee received unit doses from a licensed nuclear pharmacy.

This inspection included in-office review through September 25, 2018, to review information requested on August 3 and 27 and September 7, 2018 and received on August 3 and 7, and September 11 and 21, 2018, related to training, personnel monitoring, and audits. The inspector also reviewed the licensee's corrective actions taken in response to a SL IV violation of 10 CFR Sections 20.1801 and 20.1802 identified during the previous followup inspection to escalated enforcement. The violation is considered closed.

While no violations of NRC requirements were identified during this inspection, several performance indicators revealed that the licensee experienced financial difficulties. See Section 4.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130, "Nuclear Medicine Programs, Written Directive Not Required"

Focus Areas Evaluated: All

This inspection consisted of interviews with licensee personnel, a review of selected records, a tour of the nuclear medicine department, and independent measurements. The inspector observed the technologist inject two unit doses for cardiac stress (treadmill) and rest imaging procedures. The inspector also observed the technologist perform end-of-day exposure rate surveys using a calibrated survey meter.

The inspector examined the sealed sources in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities. The inspector observed that the licensee posted a copy of NRC Form 3. The inspector also observed that the areas where licensed material was used and stored were appropriately posted with "CAUTION-RADIOACTIVE MATERIALS" signs. The hot lab was also posted with emergency/decontamination procedures.

The licensee possessed a dose calibrator however the licensee relied on the radiopharmacy's assay, corrected for decay. The licensee ceased performing quality assurance tests on its dose calibrator unit but according to the technologist he still assayed the doses based on his personal professional practice. The inspector discussed actions the licensee should consider if the dosage assay readings differed from the decay values.

A review of the dosimetry reports for 2014 to YTD 2018, showed a consistent reading for the whole body and the extremity dosimeters as "non-detectable" or 0 millirem annually. The inspector inquired about the exposure data and expressed concern that the readings were not as expected, based on the workload. The licensee offered no explanation for this monitoring data.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Survey Instrument Used: Canberra UltraRadiac, NRC Tag No. 33558G
Calibration Date: 1/23/2018

The inspector performed direct radiation measurements in and around the licensee's hot lab (including the L-block and waste storage areas), treadmill and stress testing lab and the imaging room. All radiation levels were indistinguishable from background. All survey measurements were comparable to the licensee's survey results.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The NRC had previously attempted to conduct an inspection on April 26, 2018, however no patient studies were performed that day and the technologist was not on site. The previous inspector informed the office manager of concerns that he observed during this attempted inspection including: (1) elevated radiation levels in the nuclear medicine hot lab due to an excessive amount of contaminated biohazard wastes; (2) difficulty locating records; and (3) the housekeeping in the department.

At the time of the initial onsite inspection on July 12, 2018, the licensee's consultant had ceased providing services to the clinic in November 2017 (following the last program audit) due to nonpayment. The inspector observed several performance indicators in program areas where the NRC had previously identified violations involving the following:

(1) Efficiency checks of the well counter used to assay wipe tests for packages and area surveys had not been performed since May 2017 (this was an annual requirement under License Condition 14.A.);
(2) Leak tests of sealed sources had not been performed at 6 month intervals (Title 10 of the *Code of Federal Regulations* (CFR) 35.67(b)(2)). However, following the inspection, the licensee's new consultant clarified that these sources were considered "in storage" or had since decayed to exempt quantities that no longer required leak testing;
(3) Semi-annual physical inventories of sealed sources had not been performed since the former consultant's audit in November 2017(10 CFR 35.67(g)); and
(4) The licensee had no records of hazmat training for the technologist who prepared "empty" packages for shipment to the radiopharmacy (10 CFR 71.5(a) / 49 CFR 172.704(d))

These tasks were previously performed by the consulting physicist during his audits; however, the consultant ceased these services due to nonpayment. In addition, during the inspector's review of dosimetry reports from the vendor, she noted that the licensee only had reports current as of November 2017. The inspector informed the licensee of the requirement to retain records of individual monitoring results (10 CFR 20.2106(a)). In addition, on July 12, 2018, the inspector observed that the nuclear medicine technologist was wearing dosimetry from a previous monitoring period. Specifically, the technologist wore a whole body dosimeter for the May 2018 period and an extremity badge for the April 2018 period. A review of the application and supporting materials for the license contained no requirements to provide dosimetry at a specified frequency of exchange. Discussions with the licensee revealed that dosimetry was previously exchanged at monthly intervals; however, the licensee was behind in payment to the vendor. Consequently, the vendor halted all services effective in May 2018 and withheld reports. The licensee was prompted by the inspector to reconcile all past due payments

in July 2018 to resume dosimetry services. As of September 2018, the licensee obtained all monitoring reports from the dosimetry vendor.

In response to the initial inspection findings (described above), the licensee retained the services of another consulting firm. The new consultant conducted a review of the licensee's radiation protection program on July 27, 2018. The new consultant identified the same performance indicators described above. According to the licensee, they will retain this new consultant to conduct periodic program audits; the licensee did not specify a frequency for these audits. The licensee possessed an Orbiter gamma camera, c.1990. The technologist informed the inspector that they were unable to conduct daily flood source and weekly bar phantom testing for the camera due to the age of their cobalt-57 source that had decayed beyond useful counting. The licensee stated that there was not a budget to purchase a new flood source at this time. The licensee's new consultant recommended to resume these QA/QC checks on the camera to maintain its clinic accreditation.

The owner offered that his practice services patients whose insurance reimbursements are low which affect the cash flow into the clinic business. The owner stated that the former consultant dropped services to him due to lack of payment. He acknowledged that he was behind in payment to the dosimetry vendor and that was probably the reason why he did not receive reports since November 2017. The inspector discussed these concerns about the financial stability of the clinic and the management oversight of the radiation safety program with the owner. The initial on-site inspection on July 12, 2018, prompted the licensee to search for and retain a new consultant to resume performance of the periodic radiation safety tasks. The inspector reminded the licensee that the overall responsibility for maintaining the radiation safety program lies on the licensee management rather than a consultant.

5. PERSONNEL CONTACTED:

Nazir Ahmad, Medical Assistant, Sonographer
Dan Burgard, CNMT
#Kevin Miller, Office Manager
#Jawed H. Siddiqui, M.D., Radiation Safety Officer

Attended exit teleconference on September 25, 2018.

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