

**Metro Cardiovascular Inc.
11115 New Halls Ferry Rd.
St Louis, MO 63033**

August 8, 2014

U.S. Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

RE: NRC License 24-32636-01

Subject: Response to Apparent Violations in NRC Report 03037587/2013001 (DNMS; EA-14-072)

1. Report Section 2.2: Failure to perform annual calibration of a survey meter.
 - a. We did not have a complete grasp of the timeliness of this requirement or the controls in place to make sure the appropriate arrangements were made to remain compliant.
 - b. We immediately had a licensed firm perform the required calibration.
 - c. We have made ongoing arrangements with that same firm to perform these services at our facility before the current annual calibration due date.
2. Report Section 3.2: Use of uncalibrated survey meter for waste disposal surveys.
 - a. Due to our contractual working relationship with the Nuclear Medicine Technologist there was not good communication on the identification of this issue prior to, during or after the fact. There is no excuse for this issue and we understand that it cannot be tolerated at any time in the future.
 - b. We immediately had a license firm perform the required calibration.
 - c. We have provided training to the Nuclear Medicine technologists that there are no excuses for performing regulated work of any kind with required

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equipment that is not properly calibrated. The technologist is authorized to contact the RSO and Consultant if any equipment is getting close to their expiration date. All calibration will be completed prior to the one year expiration date of the current calibration. Under no circumstance will radiation work be performed if the required instrumentation is not properly calibrated in a timely manner. Patients and work must be canceled until the instrument is properly calibrated or loaner equipment is on site.

3. Report Section 4.2: Dose Calibrator Linearity.

- a. Our Nuclear Medicine Technologist works on site only when patients are available. We did not have a good handle on a system to make sure that this routine compliance issue was completed in a timely manner.
- b. Linearity was performed as soon as possible after identification. The system was confirmed as operating in a linear fashion.
- c. Our radiation consultant has developed a quarterly excel spreadsheet report that we use to provide the time decay linearity data. Additional personnel on site have been provided the basic radiation safety training and steps to retrieve the linearity data when our technologist is not on site. The consultant completes the calculation and provides a quarter report for our files. This test is on a reminder system to have it completed on a quarterly basis. I review and sign the documentation.

4. Report Section 5.2: Well counter efficiency.

- a. I was not properly involved with the operation of our Nuclear Medicine Hot Lab. I did not understand the importance of the performance of this task in a timely manner. I did not properly communicate or delegate the scheduling of this task to my staff.
- b. I had our consultant on site to perform this test as soon as possible. The instruments calibration was verified and the current efficiency determined.
- c. We have confirmed ongoing arrangements with our consultant to perform these services at our facility within the annual requirement for this instrument.

5. Report Section 6.2 item 1: Sealed Source Leak Tests.

- a. I was not properly involved with the operation of our Nuclear Medicine Hot Lab. I did not understand the importance of the performance of this task in a timely manner. I did not properly communicate or delegate the scheduling of this task to my staff.
- b. I had our consultant on site to perform this test as soon as possible. The leak test confirmed that our two gamma emitting sources greater than 100uCi are not leaking.
- c. This test is performed annual by the consultant during his annual calibration and audit visit. Our consultant either stops by on the six month schedule to do the test or has the kits dropped off so that our Nuclear Medicine technologists can perform the test. The consultant has performed the testing for the past year. I am reviewing and signing the certificates.

6. Report Section 6.2 item 2: Sealed Source physical inventories.

- a. I was not properly involved with the operation of our Nuclear Medicine Hot Lab.
- b. I had our consultant on site to perform this test as soon as possible. The documentation confirmed that the sources were all present at the location designated. The material is secured in my Nuclear Medicine Hot Lab. Only authorized personnel are allowed in this room.
- c. We are now performing and documenting this inventory on a quarterly basis. We understand that the regulation only requires the test on a semi-annual basis and request that to remain our official regulatory standard. By doing this task more frequently it confirms our compliance with the regulation and provides for better documentation at our site along with the other quarterly requirements.

7. Report Section 7.2: Hazardous material training.

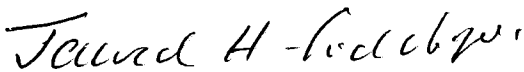
- a. I was not properly involved with the operation of our Nuclear Medicine Hot Lab. I did not confirm that our contract Nuclear Medicine Technologists was maintaining his qualifications to work.

- b. I had our consultant provide the required DOT HazMat training to my Technologist. This training is good for three years.
 - c. My Nuclear Medicine technologist is required to complete the DOT training as provided by our consultant for this specific site every three years. Documentation of this training will be maintained on file. This is an item that will be part of our annual review.
8. Report Section 8.2: Failure to perform an annual program audit.
- a. I was not properly involved with the operation of our Nuclear Medicine Hot Lab.
 - b. I had our consultant perform an annual audit of my radiation safety program. He provided specific training with me on each of the areas that were reviewed. He also provided additional RSO training based on his RSO experience at several locations.
 - d. My consultant will perform this audit on an annual basis during the calibration visit. He provides me with an briefing on the program following his visit.
9. RSO Duties and responsibilities.
- a. I acknowledge that I did not perform the duties and responsibilities as the RSO for my license during the period covered during this inspection.
 - b. There is no excuse for the lack of my involvement during this period. This inspection has been an eye opener for me. I now understand the importance of oversight for the program. I had intended for my consultant to provide the needed oversight during this period but due to communication issues with my staff and my noninvolvement the consultant visits were not properly coordinated. I have made better communication ties with my consultant and Nuclear Medicine technologist that should eliminate these issues in the future. It is still critical for me to accept and understand that my role as the RSO cannot be delegated to the extent that reliefs me of involvement with the program. I am trying to oversee the operation in a more hands on approach. My consultant and NMT can inform me directly of any issues with the radiation safety program. The NMT and consultant are free to communicate with each other directly to prevent any future issues (IE:

calibration, leak testing, inventories, etc.). I am involved with the quarterly processing of the radiation safety review program document that includes the performance of dose calibrator linearity and inventory tasks. The document also tracks the semi-annual and annual requirements for the program. The radiation safety program has improved immensely as result of the NRC inspection.

I have seen great improvement in my radiation safety program since the NRC inspection. I can only apologize for my short comings and promise to remain vigilant with my involvement with the radiation safety program in the future. I have learned much about the duties and responsibilities of the RSO for my program over the past year. I do not know everything that I should but with the relationships that I have established and changes implemented, my radiation safety program will continue to improve and exceed the expectations of your organization not just during inspections but on each day that radioactive material is used in my facility. Thank you very much for your helpful and deserved criticisms of my program. I acknowledge them all and will do better in the future.

Sincerely,

A handwritten signature in cursive script, reading "Jawed H. Siddiqui".

Jawed Siddiqui, M.D.

Owner/Radiation Safety Officer

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