



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, ILLINOIS 60532-4352

September 30, 2014

EA-14-072

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY – \$3,500, METRO CARDIOVASCULAR DIAGNOSTICS; NRC ROUTINE INSPECTION REPORT NO. 03037587/2013001(DNMS) AND OFFICE OF INVESTIGATIONS REPORT 3-2013-024

Dear Dr. Siddiqui:

This letter refers to a U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI) investigation initiated on June 19, 2013, and completed on April 29, 2014, to review a number of unresolved items identified during an inspection conducted on April 18 and 19, 2013, at your facility in Florissant, Missouri, with continued in-office review through July 5, 2013. The exit meeting for this inspection was held on July 8, 2013. The results of the inspection were provided in NRC inspection report No 03037587/2013001(DNMS) dated August 5, 2013. The inspection report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML13217A290. On July 1, 2014, you were informed of the results of the OI investigation and the existence of apparent violations requiring lasting and effective corrective actions. Details regarding the apparent violations were provided to you in a letter dated July 10, 2014, which also provided you with a synopsis of the OI investigation. This letter can be found in ADAMS at accession number ML14195A300. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

In the July 10, 2014, letter transmitting the results of OI investigation and providing the apparent violations, the NRC provided you with the opportunity to address the apparent violations in one of three ways: (1) by providing a written response; (2) by requesting a predecisional enforcement conference; or (3) by attending an alternative dispute resolution (ADR) session. In a letter dated August 8, 2014, you provided a written response to the apparent violations.

Based on the information developed during the inspection, the investigation, and the information that you provided in your response dated August 8, 2014, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report and in the NRC letter dated July 10, 2014, referenced above. Specifically, the NRC identified that a Metro Cardiovascular Diagnostics employee willfully used a survey meter that was out of calibration to perform waste disposal surveys in June and November of 2012. The NRC determined the cause of this violation to be the employee's decision to continue with the waste disposal process, although he was aware that the survey meter was out of calibration. Willful violations are, by definition, of particular concern to the NRC, because the NRC's

regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor. Willful violations cannot and should not be tolerated by either the NRC or a licensee. Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III. The NRC determined that the remaining violations were not willful. The violations were listed in the NRC letter dated July 10, 2014, including failure to: (1) calibrate the survey meter; (2) verify the linearity of the dose calibrator; (3) verify the efficiency of the well counter; (4) perform sealed source leak tests; (5) perform sealed source physical inventories; (6) maintain records of hazardous material (hazmat) training; (7) perform an annual audit; and (8) implement the radiation safety program. The NRC determined that the violations stemmed from a common root cause, which appeared to be the failure of the radiation safety officer to pay sufficient time and attention to the radiation safety program. The NRC is concerned about these violations, because they are indicative of a failure to provide adequate management oversight of radiation safety. The NRC license issued to Metro Cardiovascular Diagnostics entrusts responsibility for radiation safety to its management and particularly to its radiation safety officer, and the NRC expects effective oversight of its licensed programs. Each NRC licensee has the responsibility to protect the public health and safety by ensuring that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and corrected expeditiously. Because these violations stemmed from a common cause, they have been grouped into a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for each Severity Level III violation or problem.

Because the first Severity Level III violation was determined to be willful, the NRC considered whether credit was warranted for both *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The violation was identified by the NRC; therefore, credit is not warranted for *Identification*. In regard to *Corrective Action*, the NRC considered the information you provided in your letter dated August 8, 2014. Your staff's immediate corrective actions were to calibrate the meter. Upon doing that, your staff verified that the meter had remained in calibration such that the waste disposal surveys were accurate. For long-term actions to prevent recurrence, you retrained your technologist on the correct protocol of what should be done if the meter's calibration expired. This included ensuring your technologist recognized that he was authorized to contact both the radiation safety officer and the consultant if any equipment was approaching its calibration due date. In addition, you set up a full service contract with the consultant for ongoing routine service. You also established a firm policy that all patients and work must be canceled until the instrument is properly calibrated or a loaned, calibrated survey instrument is on site. On the basis of these corrective actions, the NRC determined that *Corrective Action* credit was warranted. The civil penalty assessment of this violation resulted in a civil penalty of \$3,500.

Because the remaining violations constituting the common-cause Severity Level III problem were not willful, the NRC assessed whether you had escalated action within the last two years or two inspections. Based on your lack of escalated history, the NRC determined that the *Identification* assessment was not applicable for these remaining violations. In regard to *Corrective Action*, the NRC considered the information you provided in your letter dated August 8, 2014. Your staff's immediate corrective actions were to restore compliance by

performing calibrations, leak tests, verifications, linearity tests, surveys, inventories, training, and audits. For long-term actions to prevent recurrence, you have established a more rigorous system to interact with your consultant to ensure that the required calibrations, tests, surveys, inventories, training, and audits are being performed. You also undertook additional training in regard to what were radiation safety officer duties and have become more involved in the nuclear medicine program. On the basis of these corrective actions, the NRC determined that *Corrective Action* credit was warranted. The civil penalty assessment of this problem resulted in no civil penalty.

Therefore, to emphasize that willful violations of NRC requirements cannot be tolerated, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$3,500 in this case. In addition, issuance of both the Severity Level III violation and problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the inspection report, in the NRC letter dated July 10, 2014, and in your letter dated August 8, 2014. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

If you disagree with the violation or problem, you may deny them, as described in the Notice, or you may request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process agree to use ADR, they select a mutually agreeable, neutral mediator and share equally the cost of the mediator's services. Generally, the NRC is willing to discuss the resolution of three potential issues: (1) whether violations occurred; (2) the appropriate enforcement action; and (3) the appropriate corrective actions for the violation. Additional information concerning the NRC's ADR program can be found at <http://www.internal.nrc.gov/OE/ADR/post-invest-adr-home.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance, as necessary. Please contact the ICR at (877) 733-9415 within 10 days of the date of this letter, if you are interested in pursuing this issue through the ADR program. If you decide to pursue ADR, please also contact Mr. Steven Orth, Enforcement Officer, within 10 days of the date of this letter at (630) 810-4373. Mr. Orth can provide additional information about the program.

J. Siddiqui

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in ADAMS. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

/RA by Darrell J. Roberts for/

Cynthia D. Pederson
Regional Administrator

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

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee Only)

cc w/encl 1: State of Missouri
State of Illinois

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Metro Cardiovascular Diagnostics
Florissant, Missouri

Docket No. 03037587
License No. 24-32636-01
EA-14-072

During an NRC inspection conducted on April 18 and 19, 2013, with continued review through July 5, 2013, along with an NRC investigation conducted from June 19, 2013, to April 29, 2014, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and Title 10 of the Code of Federal Regulations (10 CFR) Section 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

NRC Materials License 24-32636-01, Condition 14 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 11 of the license 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 implemented the model procedure in Appendix W, "Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return," of NUREG 1556, "Consolidated Guidance About Materials Licenses," Volume 9, "Program-Specific Guidance About Medical Use Licenses," which 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.
3. Monitor in a low-level radiation (<0.05 millirem per hour) area away from all sources of radioactive material, if possible."

Contrary to the above, 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 14c s/n 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.

This is a Severity Level III violation (Section 6.3)
Civil Penalty - \$3,500 (EA-14-072)

II. Violations Not Assessed a Civil Penalty

- A. 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, 2012, and April 22, 2013, the licensee failed to calibrate the survey instrument used to show compliance with 10 CFR Part 35 annually. Specifically, the licensee last calibrated its Ludlum 14c survey instrument, serial number 248466, on May 26, 2011, and did not calibrate it until April 23, 2013, an interval greater than annually.

- B. NRC Materials License 24-32636-01, License Condition 14 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 9 of the license 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 by May 25, 2012.

- C. NRC Materials License 24-32636-01, License Condition 14 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 license application states, "We have developed an[d] 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, 2012, 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, between June 15, 2012, and April 22, 2013, the licensee failed to test its sealed sources for leakage at intervals that did not exceed 6 months, and no other interval was approved. Specifically, records indicated that a leak test was conducted on December 15, 2011, but no other leak tests were conducted until April 23, 2013. The interval between leak tests exceeded 6 months.

- 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, between June 15, 2012, and April 22, 2013, 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 nuclear medicine technologist 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, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, 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 radiation safety officer failed to ensure that radiation safety activities were being performed in accordance with licensee-approved procedures and regulatory requirements. Specifically, the radiation safety officer 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) an annual radiation protection program review was performed.

This is a Severity Level III problem (Section 6.3).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and to prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03037587/2013001(DNMS) dated August 5, 2013, the NRC letter dated July 10, 2014, and in your response dated August 8, 2014. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201, if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-14-072," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

You may pay the civil penalty proposed above, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, a statement ("Statement as to Payment of Civil Penalty") indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission within 30 days of the date of this Notice. Should you fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should you elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, your response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. Your attention is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., "Reply to a Notice of Violation," "Statement as to Payment of Civil Penalty," and "Answer to a Notice of Violation," should be addressed to: Patricia K. Holahan, Acting Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to Cynthia D. Pederson, Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352.

The responses noted above will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the responses should not include any personal privacy, proprietary, or safeguards information so that they can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 30th day of September, 2014.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in ADAMS. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

/RA by Darrell J. Roberts for/

Cynthia D. Pederson
Regional Administrator

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

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee Only)

cc w/encl 1: State of Missouri
State of Illinois

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* See previous concurrences.

FILE NAME: EA-14-072 Metro Cardiovascular Final Action.docx

OFFICE	RIII	RIII	RIII	D:FSME	D:OGC	D:OE	RIII	RIII
NAME	Lougheed* PR Pelke	McCraw*	Louden* Giessner	Henderson ¹ Burgess	Scott ² Monteith	Holahan ³ Norman	Orth	Roberts for Pederson
DATE	09/10/14	09/10/14	09/10/14	09/12/14	09/22/14	09/23/14	09/29/14	09/29/14

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¹ FSME concurrence provided via email from M. Burgess on September 12, 2014

² OGC "No Legal Objection" provided via email from E. Monteith on September 22, 2014

³ OE concurrence provided via email from K. Norman on September 23, 2014