



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

December 16, 2015

EA-15-113

Bradley D. Bastow, D.O.
c/o Mr. Philip Troy, Esq.
217 Ash Court
Wexford, PA 15090-7817

SUBJECT: NRC FOLLOW-UP INSPECTION REPORT NO. 03035710/2014001(DNMS), AND
INVESTIGATION REPORT NO. 3-2014-016 – BRADLEY D. BASTOW, D.O.

Dear Dr. Bastow:

This letter is in reference to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 27, April 21, April 24, and May 5, 2014, with continued in-office review through June 20, 2014, at your facility in South Haven, Michigan. The purpose of the inspection was to review activities to verify that they were being performed in compliance with your NRC license and the Confirmatory Order issued to Bradley D. Bastow, D.O. on September 3, 2013. During the inspection, the NRC inspector identified two open items which are documented in detail in NRC Inspection Report No. 03035710/2014001(DNMS), dated July 30, 2014. The Inspection Report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession Number ML14212A105. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

As described in the subject Inspection Report, on April 24, 2014, during the conduct of independent surveys of your facility, the NRC inspector identified the presence of radioactive contamination in the treadmill area following a spill. On June 27, 2014, the NRC Office of Investigations (OI) initiated an investigation to determine whether a nuclear medicine technologist (NMT) at your facility deliberately provided incomplete and inaccurate information on a daily survey record after the technologist identified an elevated survey reading and did not document it. The OI investigation was completed on May 20, 2015. Based on the results of its investigation, the NRC preliminarily determined that the NMT deliberately violated procedural requirements and NRC regulations by providing incomplete and inaccurate information on a daily survey record. A factual summary of the OI Investigation Report is included in the enclosure.

Based on the results of the inspection and investigation, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The first apparent violation involves the deliberate failure by the NMT to maintain complete and accurate information as required by Title 10 of the *Code of Federal Regulations* (CFR) 30.9 (a). Specifically, the NMT failed to annotate an elevated survey reading on a daily survey record

following a spill on April 23, 2014, in accordance with the licensee's Area Survey Procedures and Condition 15.A of Amendment 02 to the NRC license 21-32316-01. The second apparent violation involves the failure to report the spill and complete a Radioactive Spill Report and Radioactive Contamination Survey as required by the licensee's Emergency Procedures and Condition 15.A of Amendment 02 to NRC license 21-32316-01. The results of the NRC inspection and the investigation, the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with Mr. Troy, your attorney, on December 15, 2015.

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. In addition, please be advised that the number and characterization of the apparent violations may change as a result of further NRC review. Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violations (characterized as open items in NRC Inspection Report No. 03035710/2014001(DNMS)); (2) request a Pre-decisional Enforcement Conference (PEC); (3) request Alternative Dispute Resolution (ADR); or (4) request termination of your NRC license.

If you choose to provide a written response to the apparent violations, it should be clearly marked as a "Response to Apparent Violations, NRC Inspection Report 03035710/2014001(DNMS); EA-15-113," submitted within 30 days of the date of this letter, and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC web site at: <http://www.nrc.gov/reading-rm/doccollections/gen-comm/info-notices/1996/in96028.html>. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Additionally, your written response should be sent to the NRC's Document Control Center, with a copy to Cynthia D. Pederson, Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Rd, Suite 210, Lisle, IL 60532-4352. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violations and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The topics discussed during the conference may include the following: information to determine whether the violations occurred, information to determine the significance of the violations, information related to the identification of the violations, and information related to any corrective actions taken or planned to be taken.

You may also request ADR with the NRC in an attempt to resolve the willful apparent violations. The term ADR generally encompasses various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing ADR.

If you choose to terminate your NRC license, the NRC will consider using discretion to not impose any monetary civil penalty associated with these apparent violations upon notification, in writing, of a successful completion of activities associated with shutdown of your facility at 950 Blue Star Highway, Suite 1-2, South Haven, Michigan, and termination of your NRC license number 21-32316-01. Your written notification should include information specified in our letter dated November 4, 2015 (ML15308A611) with reference to case number EA-15-113. If the written notification is not received within 30 days from the date of this letter or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision. Should you request an NRC license in the future, any monetary civil penalty associated with these apparent violations will be reinstated.

Please contact Mr. Aaron McCraw at 630-829-9650 within 10 days from the date of this letter to notify the NRC of how you intend to respond to the apparent violations.

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 or from ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

B. Bastow

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Please feel free to contact Mr. Ryan Craffey of my staff if you have any questions regarding the inspection and the two open items described in the subject Inspection Report. Mr. Craffey can be reached at 630-829-9655.

Sincerely,

/RA Julio F. Lara Acting for/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-35710
License No. 21- 32316-01

Enclosure:
Factual Summary

cc: State of Michigan
Philip Troy, Esq.

FACTUAL SUMMARY OF OFFICE OF INVESTIGATIONS REPORT 3-2014-016

On June 27, 2014, the U.S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a Nuclear Medicine Technologist (NMT), University Nuclear & Diagnostics (UND), deliberately provided incomplete and inaccurate information on a daily survey record. The NRC completed its investigation on May 20, 2015.

On April 24, 2014, an NRC inspector identified the presence of radioactive contamination in Dr. Bradley Bastow's medical facility, Cardiology II, at the stress treadmill area. The inspector's survey meter responded to contamination upon entry into the area and the inspector identified a spill on the right sill of the treadmill. Licensee records indicated that the last administrations of Technetium-99m for the week had been performed the day before (April 23). The daily radiation survey record for April 23, 2014 did not indicate any elevated radiation readings in the treadmill area as the spaces were blank; however, the record contained radiation readings for other areas of the facility.

During an interview with OI, the NMT admitted that a spill occurred on April 23, 2014. A patient who was earlier injected with radioactive material continued to bleed after the intravenous fluid drip (IV) was taken out and some blood spilled on the treadmill. The NMT surveyed the room and the treadmill area and received a reading of approximately 5 millirems on his meter. The NMT stated that he had attempted to inform the Radiation Safety Officer (RSO) of the spill, but was unable to find him. Then, he locked the room and informed another employee, a billing coordinator for the office, of the spill and not to let anyone in. The technologist explained that he estimated that the radioactive material would decay within the next 48 hours and the room would read background before new patients were to be tested. When asked why he did not post the area, the NMT replied that he did not have any signs to post; however, he noted the room was posted when he returned to work. Further, when asked why he did not record the elevated radiation reading on April 23, he stated that the area needed to be monitored through any clean up efforts to ensure there is no contamination and that he was planning to record the initial survey readings and any following survey results on one form (the NMT believed the information would be more organized this way). Additionally, when challenged by OI regarding documenting survey results from different days on a daily survey form, the NMT acknowledged there was a separate "spill form," however, he never filled one out as he wanted to check with the RSO the next day. The individual added that he did not notify the RSO electronically as he was relying on the billing coordinator to provide the information to the RSO. Although the NMT denied any intent to conceal the spill, he stated that he did not have a very good explanation for not documenting the elevated survey reading the day of the spill.

Based on the evidence gathered during the OI investigation, it appears that an NMT deliberately violated NRC requirements and license conditions by failing to maintain complete and accurate information in accordance with 10 CFR 30.9 (a). Specifically, the NMT failed to annotate an elevated survey reading following a spill on April 23, 2014.

Enclosure

B. Bastow

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Please feel free to contact Mr. Ryan Craffey of my staff if you have any questions regarding the inspection and the two open items described in the subject Inspection Report. Mr. Craffey can be reached at 630-829-9655.

Sincerely,

/RA Julio F. Lara Acting for/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-35710
License No. 21- 32316-01

Enclosure:
Factual Summary

cc: State of Michigan
Philip Troy, Esq.

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DATE	11/23/15		11/23/15		11/23/15		12/16/15	
OFFICE	RIII ORA	E	OE	E	OGC	E	RIII DNMS	E
NAME	JHeck		PHolahan ¹		CScott ²		JGiessner JLara for	
DATE	11/30/15		11/09/15		11/07/15		12/16/15	

OFFICIAL RECORD COPY

¹ OE concurrence provided via e-mail from T. Marenchin on December 9, 2015

² OGC "no legal objection" provided via e-mail from S. Lewman on December 7, 2015

Letter to Bradley D. Bastow, D.O. from Mr. John B. Giessner dated December 16, 2015

SUBJECT: NRC FOLLOW-UP INSPECTION REPORT NO. 03035710/2014001(DNMS) AND RESULTS OF NRC OFFICE OF INVESTIGATION REPORT NO. 3-2014-016 – BRADLEY D. BASTOW, D.O.

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