April 18, 2013

EA-13-026

Mr. Avital Soffer
Co-owner
University Nuclear & Diagnostics, LLC,
10396 W. State Road 84, Suite 104
Davie, FL 33324

SUBJECT: RESULTS OF NRC INVESTIGATION REPORT; NO. 03035710/2012001(DNMS) - UNIVERSITY NUCLEAR & DIAGNOSTICS, LLC

Dear Mr. Soffer:

The U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection on February 28, and April 3, 2012, with continued in-office review through May 24, 2012, at Bradley Bastow, D. O., 950 Blue Star Highway, South Haven, Michigan, for whom University Nuclear & Diagnostics, LLC, (UND) was contracted to implement the Nuclear Medicine Program. The details of the inspection were documented in NRC Inspection Report No. 030-35710/2012-001 (DNMS) issued on December 19, 2012. During the inspection, several unresolved items were identified that required further NRC review. The NRC Office of Investigations (OI) began an investigation on April 2, 2012, into the issues, and the investigation was completed on January 31, 2013. Enclosure 1 contains a factual summary of the NRC investigation.

Based on the results of the NRC inspection and investigation, one apparent violation was identified and is 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. This apparent violation involved deliberate misconduct by UND that caused NRC licensee Bradley Bastow D.O. to be in violation of NRC requirements. Specifically, UND failed to maintain a calibrated survey instrument, instructed its employees to document surveys when the survey instrument was not working or not on site, failed to perform required contamination surveys (i.e., "wipe tests") because the well counter was not working and the survey meter was also not working or not on site, failed to perform dose calibrator linearity tests, and falsified annual records.

The above issues appear to be examples of an apparent violation of Title 10 of the Code of Federal Regulations (CFR), 30.10(a)(1) which prohibits, in part, contractors of an NRC license from engaging in deliberate misconduct that causes the NRC licensee to be in violation of NRC regulations. The actions of UND employees appeared to cause Dr. Bastow to be in violation of NRC regulations. A copy of the letter to Dr. Bastow is in Enclosure 2.

Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for this inspection finding at this time. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed at the inspection exit meeting on November 28, 2012.

As your facility has not been the subject of escalated enforcement actions within the last two inspections and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in this letter within 30 days of the date of this letter; (2) request a Predecisional Enforcement Conference (PEC); or (3) request Alternative Dispute Resolution (ADR). Please contact Tamara Bloomer at 630-829-9627 within ten days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Report No. 030-35710/2012-001 (DNMS) EA-13-026, and should include, for the 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 to avoid further violations; and (4) the date when full compliance will be achieved. 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 request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. We encourage you to submit supporting documentation as to the corrective actions you have taken at least one week prior to the conference in an effort to make the conference more efficient and effective. The topics discussed during the conference may include the following: (1) information to determine whether violations occurred; (2) information to determine the significance of the violations; (3) information related to the identification of the violations; and (4) information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions, as well as your prior enforcement history, will be considered in assessing any civil penalty for the apparent violations. If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, it will be closed to public observation because the apparent violations are based on an NRC OI Report that has not been publicly disclosed and pertains to whether individuals committed wrongdoing.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing 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/alt-dispute-resolution.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 ten days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In addition, NRC has significant concerns regarding the work environment at UND that allowed these apparent violations to occur and/or persist. In its policy statement, "Freedom of Employees to Raise Safety Concerns without the Fear of Retaliation," dated May 14, 1996, the Commission stated that it expects licensees to maintain an environment where employees are encouraged to raise safety concerns and where concerns are promptly reviewed and properly resolved. Based on the evidence gathered by OI in this case, it appears that staff were uncomfortable raising issues and, when raised, issues were not resolved. More significantly, there is also substantial evidence to conclude that a pervasive environment of intimidation existed that resulted in staff fearing for their jobs if they raised safety or regulatory concerns. As such, when formulating your corrective actions to support either a PEC or ADR, we request that you address your perspectives on the safety conscious work environment that existed within your organization at the time the apparent violations occurred and any actions you have taken to ensure your employees currently feel free to raise concern to organization's attention without fear of retaliation.

Please be advised that the number and characterization of apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter, including resolution of the unresolved items identified during the inspection.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

Please feel free to contact Mr. Robert Hays of my staff if you have any questions regarding this inspection. You can reach Mr. Hays at 630-829-9819.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Enclosures:
1. Factual Summary of NRC Investigation
2. Letter to Dr. B. Bastow

cc w/encl: State of Michigan, Director
Radiation Control Program
State of Florida, Director
Radiation Control Program

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Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Enclosure:
Factual Summary of NRC Investigation

cc w/encl: State of Michigan, Director
Radiation Control Program
State of Florida, Director
Radiation Control Program

DISTRIBUTION w/encl:
See next page

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Note 1: OE review and concurrence provided by 4/16/13 email from T. Marenchin. OGC review and NLO provided by 4/11/13 email from C. Hair.

Letter to Avital Soffer from Anne T. Boland dated April 18, 2013

SUBJECT: RESULTS OF NRC INVESTIGATION REPORT NO. 03035710/2012002(DNMS) – UNIVERSITY NUCLEAR & DIAGNOSTICS, LLC

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FACTUAL SUMMARY OF NRC INVESTIGATION

On April 2, 2012, the U.S. Nuclear Regulatory Commission's Office of Investigations (OI), Region III Field Office, initiated an investigation regarding operations at Bradley D. Bastow, D. O., (Bastow) a cardiology office where University Nuclear and Diagnostics (UND) has a contract to supply nuclear medicine technicians (NMT's) and equipment. The purpose of the OI investigation was to determine whether the employees for either Bastow or UND deliberately violated NRC requirements by failing to: (1) perform dose calibrator linearity tests and record the net activity, date and time for the dose calibrator linearity tests; (2) perform an annual review and maintain annual records; (3) calibrate survey instruments and maintain calibration records; (4) perform area surveys and maintain area survey records; and 5) perform package receipt surveys, and maintain package receipt survey records.

The investigation was completed on January 31, 2013, and was documented in OI Report No. 3-2012-017.

For the first concern, based upon the evidence developed, the investigation substantiated the concern that a contract consultant, representing UND, working for Bastow, and the Radiation Safety Officer (RSO) for Bastow both willfully failed to perform dose calibrator linearity tests. Furthermore, the investigation substantiated that the contract consultant and the RSO both willfully failed to accurately record the net activity, date and time for the dose calibrator linearity test. The investigation showed that no technetium-99m was ordered from the supplier on either August 5 or November 30, 2011, yet dose calibrator linearity tests were provided for those dates. During his interview, the contract consultant stated that he wrote the numbers on the same form and made it look nicer on templates. The contract consultant provided some worksheets; however, there were discrepancies between the dates on the worksheets provided by the contract consultant and the dates on the records in Bastow's office. The investigation also showed that the contract consultant claimed to be using data from a Calicheck system. However, the contract consultant only had two Calichecks, and the dose calibrator linearity test records provided showed six different sets of calibration factors. When asked during the investigation, the contract consultant stated multiple times that he got the calibration factors "from the computer" or "came from the back of the computer" but could not otherwise explain how or why the numbers changed despite being repeatedly asked. During his interview, the RSO stated he didn't do the tests and didn't know how to do the tests. Additionally, the RSO had not signed the linearity tests, as required by a condition of the license.

For the second concern, based upon the evidence developed, the investigation substantiated the concern that the contract consultant deliberately, and the RSO willfully, failed to perform the annual ALARA review. The investigation also substantiated that the contract consultant deliberately, and the RSO willfully, failed to maintain an accurate annual record. The investigation showed that the information provided in the annual "as low as reasonably achievable" or ALARA report was incorrect. Specifically, the annual ALARA report, dated November 30, 2011, contained the following inaccurate information: (1) the report stated that receipt of radioactive material documents were reviewed. However, this could not have been done because had it been done, the contract consultant would have seen receipt documents that stated that the survey meter and well counter were not functioning; and (2) the report stated that the most recent state inspection was reviewed. However, Bastow is not inspected by a State but rather by the NRC. The report stated that Bastow's State of Florida's Radioactive Materials License was current; however, Bastow has never had a State of Florida Radioactive Materials License. During his interview, the contract consultant stated that he did not look at those receipt records, and that he was surprised that the NRC was able to find the reports. The contract consultant was asked if he checked the survey meter during the ALARA review. The

contract consultant replied yes, of course. The contract consultant further stated that the survey meters are always functioning. Travel records indicated that the contract consultant traveled to Bastow's office, in South Haven, Michigan on November 24, 2011, and there is an ALARA checklist completed on this date. However, records indicated that the survey meter was offsite from October 5, 2011, to November 28, 2011. Therefore, the contract consultant could not have checked the survey meter as reported on the ALARA checklist, and as stated during the interview. The RSO stated that Bastow did not have a State of Florida reactor materials license. He further stated he didn't study the report by any means. The RSO stated that he hadn't been involved in doing an annual audit since his nuclear physicist class 25 years ago, and that he had not observed the contract consultant performing the annual audit.

For the third concern, the investigation substantiated that the contract consultant deliberately, and the RSO willfully, failed to perform the survey meter calibration. Furthermore, the investigation substantiated that the contract consultant deliberately, and the RSO willfully, failed to maintain accurate annual survey instrument calibration records. The investigation produced two calibration records dated August 13, 2010, and November 10, 2011. The records each contained 30 different calibration data points. The records were identical except for the date. During his interview, the contract consultant stated that if the survey meter was within range, it should show identical numbers and that was how it should be. He further stated that a lot of physicists don't even calibrate survey meters. The contract consultant also stated that he rounded his numbers. During his interview, the RSO stated that the calibrations were not signed by him, even though it had a place for an RSO signature. The RSO also stated that it was surprising that the numbers were identical, and that the odds were kind of unusual. He specifically said it was like hitting on a slot machine twice, it doesn't happen a lot. The RSO said he would have never compared the old ones to see if they're identical. The RSO also stated that he didn't do the calibration and didn't know how it was done. Neither the contract consultant or the RSO was able to answer how the calibration was performed given that records showed that the survey meter had been shipped to UND on October 5, 2011, because it was not functioning.

For the fourth concern, the investigation substantiated that the contract consultant deliberately failed to perform area surveys and sealed source area surveys, and the RSO willfully failed to perform area surveys. Furthermore, the investigation substantiated the concern that the contract consultant deliberately, and the RSO willfully, failed to maintain accurate area survey records. Interviews with multiple nuclear medicine technicians indicated that they informed the contract consultant that the survey meter was broken and that they received instructions from the contract consultant to record the daily and weekly survey numbers either as background or as very low numbers. Additionally, records showed that the survey meter had been shipped to UND on October 5, 2011, and was not returned to Bastow's office until November 28, 2011. During this time period, the contract consultant traveled to Bastow's office and purportedly performed area surveys and sealed source area surveys (as part of the annual audit). However, there was no record that the contract consultant brought a survey meter with him on the airplane. During his interview, the contract consultant denied ever being told that the survey meter was not functioning and, at one point, stated that survey meters are always functioning. The RSO stated he wasn't informed that there was no functioning survey meter. Further, the RSO stated that Bastow had records that they were still doing surveys, and that he didn't know how they did that. The RSO acknowledged that he was responsible for safe use of radiation and for overseeing things.

For the fifth concern, the investigation substantiated that the contract consultant deliberately, and the RSO willfully, failed to perform package receipt surveys. The investigation also

substantiated that the contract consultant deliberately, and the RSO willfully, failed to maintain accurate package receipt survey records. Records indicate that both UND and the RSO were informed on August 10 and 11, 2011, respectively, that the well counter used for package wipes was broken, and that UND had informed the technicians to use the survey meter to perform the package wipes. The contract consultant stated that there was absolutely no requirement for there to be a well counter. When shown the well counter on the list of equipment for the license, the contract consultant stated that just because there was a piece of equipment listed, didn't mean that they needed to use it. During his interview, the contract consultant acknowledged telling the nuclear medicine technicians to use the survey meter. The contract consultant could not explain how the nuclear medicine technicians were supposed to convert from counts per minute (CPM) to disintegrations per minute (DPM). Furthermore, as indicated above, for approximately two months, there was no survey meter available as well as no well counter. The RSO stated he wasn't aware that the well counter wasn't working or that there wasn't a functioning survey meter, and that he relied on UND for that. However, the RSO acknowledged that he was responsible for safe use of radiation and for overseeing things.