



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

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

May 13, 2014

EA-13-026

Dr. Avital Soffer  
Chief Executive Officer  
University Nuclear and Diagnostics, LLC  
10396 W State Road 84  
Suite 104  
Davie, Florida 33324

**SUBJECT: NOTICE OF VIOLATION – UNIVERSITY NUCLEAR AND DIAGNOSTICS, LLC;  
NRC INSPECTION REPORT NO. 03035710/2012001(DNMS) AND  
INVESTIGATION REPORT NO. 3-2012-017**

Dear Dr. Soffer:

This refers to a U.S. Nuclear Regulatory Commission (NRC) inspection and the subsequent Office of Investigations (OI) investigation. The inspection was conducted on February 28 and April 3, 2012, with continued in-office review through May 24, 2012, at Bradley D. 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 significance of the issues and the need for lasting and effective corrective actions was discussed with Dr. Bastow on November 28, 2012, and the results of the OI investigation were discussed with you on April 18, 2013. Details regarding the apparent violation were provided in our letter to you dated April 18, 2013, which provided you a synopsis of the OI investigation. This letter can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number [ML13108A148](http://www.nrc.gov/reading-rm/adams.html). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

On June 20, 2013, a predecisional enforcement conference was conducted in the Region III office with you, Mr. Armando Clavero, and your attorney of record at that time, to discuss the apparent violation, its significance, its root cause, and your corrective actions. The State of Florida listened to the conference. On August 9, 2013, the NRC provided you with a letter outlining the information discussed at the conference and informing you that the NRC was continuing to evaluate the information. This letter can be found in ADAMS at accession number [ML13226A459](http://www.nrc.gov/reading-rm/adams.html).

Following the conference, you provided the NRC with additional information, received via electronic and regular mail. The NRC also performed additional investigation into the matter of a second survey meter as discussed at the conference, including conducting additional interviews with current and former UND employees. This supplemental investigation was completed on February 4, 2014. A synopsis of the NRC's review into the issue of whether a second meter existed at Dr. Bastow's office during the time period from October 5 to November 28, 2011, when the normal survey meter was not in the office, and other issues left unresolved at the conference, is contained Enclosure 1.

Based on the information developed during the inspection and investigation, and after full consideration of the information that you provided during the conference on June 20, 2013, and in your submittals provided electronically on July 1, 2013, and via mail on July 3, 2013, and the supplemental investigation completed on February 4, 2014, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the Notice of Violation (Notice) in Enclosure 2 and the circumstances surrounding it is described in detail in our letter dated April 18, 2013.

Specifically, the NRC determined that the actions of employees of UND deliberately caused Bradley D. Bastow, D.O., an NRC licensee, to be in violation of NRC requirements. Title 10 of the *Code of Federal Regulations* (10 CFR), 30.10(a)(1) 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 NRC determined that UND employees failed to maintain a calibrated survey instrument in 2010 and 2011 and falsified calibration records for those years, 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 between October 5 and November 28, 2011, falsified surveys and instructed its employees to falsify surveys when the survey instrument was not working or not on site between October 5 and November 28, 2011, and falsified annual records on either October or November 24, 2011. The NRC also determined that UND employees provided incomplete and inaccurate information during the regulatory conferences held on June 20, 2013, in submittals following the conference and during the OI interviews conducted in November 2013.

The NRC determined that the root cause of the violation was the deliberate actions of UND employees. Other employees at UND, including yourself, also appeared to contribute to an atmosphere where employees did not feel free to bring up safety issues and ensure that they would be resolved. Willful violations are of particular concern to the NRC because our regulatory programs are based on licensees and their contractors acting with integrity and communicating with candor. Therefore, in accordance with the Enforcement Policy, the NRC has categorized the above violation as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is normally considered for a Severity Level III violation. This amount would then be increased or decreased, depending on the factors of *Identification* and *Corrective Action*, in order to encourage identification and correction of violations. However, the NRC also normally considers that its licensees have the primary responsibility to ensure compliance with their license and NRC regulations on the part of their contractors. For this reason, the NRC took action against the NRC licensee, Bradley D. Bastow, D. O., including issuance of a civil penalty, as part of an alternative dispute resolution settlement. A copy of the Confirmatory Order to Dr. Bastow can be found in ADAMS at accession number [ML13241A320](#). Therefore, after consultation with the Director, Office of Enforcement, the NRC proposes to not issue a civil penalty to you in this case.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may also provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Alternatively, you may request alternative dispute resolution (ADR) with the NRC if you disagree with the enforcement outcome. 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. 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 30 days of the date of this letter if you are interested in pursuing this issue through the ADR program. Please also contact Steven Orth, at 630-810-4373 if you opt to use the ADR process.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response 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>. Therefore, to the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information

A. Soffer

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required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at [http://www.nrc.gov/reading\\_rm/doc\\_collections/enforcement/actions/](http://www.nrc.gov/reading_rm/doc_collections/enforcement/actions/).

Sincerely,

*/RA/*

Cynthia D. Pederson  
Regional Administrator

Docket No. 150-00009  
Florida License No. FL 4072-1

Enclosures:

1. NRC Investigation Result  
and Conclusions
2. Notice of Violation

cc w/encls: Mr. Philip Troy, Esq.  
State of Michigan  
All Agreement States

## NRC INVESTIGATION RESULT AND CONCLUSIONS

The NRC performed an initial investigation from April 2, 2012, to January 31, 2013, regarding operations at Bradley D. Bastow, D. O., (Bastow), an NRC licensee whose cardiology office contracted with University Nuclear and Diagnostics (UND) to supply nuclear medicine technicians (NMTs) and equipment. Based on the results of the initial investigation, the NRC came to a preliminary conclusion that UND employees deliberately caused Bastow to be in violation of NRC requirements. On April 18, 2013, a letter containing a factual summary of the investigation was sent to UND. On June 20, 2013, a predecisional enforcement conference was held to allow UND to provide information relevant to the issues. As a result of information provided during the predecisional enforcement conference, the NRC's Office of Investigations conducted a supplemental investigation from July 11, 2013, to February 4, 2014. The supplemental investigation was to determine if there was evidence to support the existence of a second meter at Bastow's office for the time period of October 5 to November 28, 2011. The issue of a second meter was raised during the predecisional enforcement conference.

During the predecisional enforcement conference, UND first stated that a second meter was present, based on the serial number documented by a UND nuclear medicine technologist (NMT) on survey records. The information provided at the predecisional enforcement conference was that the UND staff brought the meter to Bastow's office. However, within days of the conference, the NRC was notified that UND had never owned a meter with that serial number. UND acknowledged that members of the UND staff had provided inaccurate information by writing down a serial number for an instrument that did not exist. UND then stated that Bastow had a second meter in his office, and UND provided a retyped portion of an electronic mail (email) message from a former NMT to support that fact. UND also provided statements from two UND NMTs, normally based in the UND home office, but who worked for several days at Bastow's office in the October to November 2011 period. These statements acknowledged writing the incorrect serial number, but also insisted that a second meter was present while they were there.

Through review of records, and through interviews and inspection as discussed below, the NRC determined that Bastow's practice had two survey meters prior to contracting with UND. Calibration records showed the presence of two meters with serial numbers of 172810 and 173094 present at Bastow's office, until approximately February 2010. The portion of the email message provided by UND indicated that the second meter was present as of August 2010. As part of the supplemental investigation, the NRC determined that the second meter originally owned by Bastow (meter with serial number 173094) was actually located at a doctor office's in Florida where UND consulted. The NRC was unable to determine exactly when the meter was first assigned to the Florida doctor's office. However, based on the information available, including the calibration documents, the NRC concluded that this meter was not at Bastow's office in October through November 2011. Additionally, based on UND's records, the NRC was unable to identify a survey meter that was owned by UND, but was currently missing.

The NRC interviewed all the contract NMTs who worked for UND at Bastow's since August 2010 until the present. The NMT who worked at Bastow's office from June to August 2010 stated that there were originally two meters at Bastow's office, but one was sent out for calibration and did not return before that NMT's employment was terminated by UND. The NMT who worked from approximately September 2010 to October 2011, stated during an OI interview that only one meter was present during the time of the NMTs employment. The NMT who worked during October to November 2011 stated that there was no meter present during the

time the NMT worked for Bastow, and, as instructed by the UND NMTs from the Florida office, the NMT documented background on the survey form. This NMT complained via e-mails to UND and Bastow about the lack of a survey meter. The NMT that worked during November to December 2011, stated that there was initially no meter present in the office and when it returned on November 28, 2011, the survey meter was not working. The NMT who currently works for the office stated during the inspection, that there was only meter at Bastow's office at the current time. The NRC verified through inspection that only one meter was currently present.

The above testimony, which consistently indicated that there was not a second meter at Bastow's office, conflicted with that of the two UND NMTs from the Florida office. The first UND Florida NMT stated that she used an out-of-calibration meter for a week but then decided to send it off for calibration. At this point, the NMT stated that she found a second meter, that it was within calibration and she started using it. The NMT was unable to provide a consistent and credible account of where the second meter was located, where the calibration records that she purportedly verified were located, why she used an out-of-calibration meter for a week if there was a second calibrated meter available, why she wrote down a serial number without verifying it, and how she arrived at that serial number, given that UND had never owned a meter with that serial number. The first UND NMT stated that she made a mistake with writing the serial number and speculated that an NMT after her must have stolen or destroyed the survey meter.

The second UND Florida NMT stated that she copied the meter serial number from the records left by first UND Florida NMT and didn't verify it or the calibration, because the first UND Florida NMT had verified it. This UND NMT also stated that she did all the doses and surveys herself and discussed how to do surveys with the person she was supposed to be training, rather than showing the trainee or having the trainee do it independently. Finally, the second UND NMT stated that she did not see the UND Chief Technical Officer at the licensee's office on October 24, 2011, although both she and the UND Chief Technical Officer were allegedly present that day and measured the same dose of technetium-99m in the same small room at approximately the same time (given the recorded dose) prior to it being given to a patient.

Despite the lack of any corroborating evidence to support that there was a second survey meter at Bastow's office, the two UND Florida NMTs consistently stated that there was a meter there, it was within calibration, and they both had made a mistake in writing down the serial number. Neither UND Florida NMTs could provide any information that verified the existence of the second meter other than their statements. The NRC concluded that the assertion of the presence of a second meter, of unknown serial number, without calibration records, that did not exist prior to or after the time period the NMTs were at Bastow's office, was not credible. Therefore the NRC concluded that the surveys recorded using meter 172818 during the October and November 2011 were falsified either by the UND Florida NMTs or at the direction of the UND Florida NMTs.

As part of the investigation, the NRC also obtained and reviewed the calibration records for the meter 172810 which was gone from Bastow's office for nearly two months. During the initial inspection and investigation, the NRC had questioned the accuracy of the calibration records dated August 13, 2010, and November 10, 2011, for the following two reasons: (1) both the 2010 and 2011 calibration results showed that the meters were perfectly within calibration and (2) both the 2010 and 2011 calibration results were performed using a cesium-137 source of

approximately 207 microcuries (in 2008). The UND Chief Technical Officer's explanation for the exact and duplicate calibration records was that he rounded off the numbers was not considered credible, as a survey meter normally varies by 10 to 15 percent. The NRC also questioned how the calibrating source had sufficient strength to provide the counts for the upper end of the meter. The UND Chief Technical Officer's explanation for this at the conference was that there was a high background in the area where he did the calibrations that provided the higher survey meter readings. The NRC did not find this explanation believable because that amount of background radiation would have adversely affected the lower readings and would not have been consistently reproducible.

The NRC determined that UND had meter 172810 recalibrated on May 14, 2012, by an outside consultant using a larger source. At that time, the meter was not functioning properly and was out of calibration such that a new Geiger-Mueller (GM) tube needed to be installed. Based on the records provided and statements made during interviews and the conference, the NRC determined that the survey meter was not actually calibrated in either 2010 or 2011 and the calibration records provided were falsified.

The NRC also reviewed information provided by the UND Chief Technical Officer about trips made to Michigan and how those correlated to leak tests, survey records, and the annual report. During the conference, UND stated that the surveys and leak tests were initially documented by hand and the UND Chief Technical Officer would later input the data into a computer, which he stated would not let him change the date to reflect the actual date of the survey. UND acknowledged that the records were inaccurate as to the date the surveys and leak tests were actually performed and that the worksheets, which were considered draft documents, reflected the actual dates. The UND Chief Technical Officer was able to provide travel records for most of the trips taken, which corresponded to the dates on the worksheets. The NRC accepted the explanation about the computer, observing that at least one formal paperwork had two different dates on it (the date at the top indicated that the record was for August 5, 2011, but the record stated that the sources were leak tested on March 5, 2012) and a draft sealed source inventory dated July 20, 2011, did not match the August 5, 2011, typed inventory – but did match the March 5, 2012, typed inventory. However, the NRC was unable to substantiate that the UND Chief Technical Officer was physically present in Bastow's Michigan office in either October or November 2011.

Specifically, although the UND Chief Technical Officer provided a portion of a bank statement which showed the use of a check card at a Holiday Inn Express in South Haven Michigan on October 25, 2011, the bank statement also showed that the same bank card was used at a local diner in Davie, Florida, on October 24, 2011. The use of the card in Florida at the same time the UND Chief Technical Officer was reportedly in Michigan conducting the annual audit caused the NRC to question whether there were multiple copies of the bank card, whether the UND Chief Technical Officer was actually in Michigan or whether the card was used to pay for the hotel for one of the NMTs (as airline and rental car information was provided for the NMT, but not hotel information). The only other travel record the UND Chief Technical Officer was able to provide for the October 2011 time period was a credit card statement that showed airline purchases, but not dates of travel, places of travel or passenger information. This credit card statement was hand-annotated to state "trip to Michigan," by one of three entries. This contrasted with other trips, where the UND Chief Technical Officer was able to provide rental car receipts, ticketed passenger receipts, or other information to show that he was in the

Michigan vicinity. When combined with the information that the serial number for the survey instrument recorded by the UND Chief Technical Officer was for a survey meter which did not exist, and with leak rate tests and sealed source survey results that indicated negative decay rates, the NRC was unable to confirm that the UND Chief Technical Officer actually completed the annual audit as stated.

## NOTICE OF VIOLATION

University Nuclear & Diagnostics, LLC  
Davie, Florida

Docket No. 150-00009  
License No. FL 4072-1  
EA-13-026

During a U.S. Nuclear Regulatory Commission (NRC) investigation conducted from April 2, 2012 to January 31, 2013, with supplemental investigation from July 11, 2013, to February 5, 2014, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* 30.10 (a), "Deliberate Misconduct," requires, in part, that any contractor (including a supplier or consultant) may not: (1) engage in deliberate misconduct that causes a licensee to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or (2) deliberately submit to a licensee information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

Contrary to the above, between August 13, 2010, and April 26, 2012, University Nuclear & Diagnostics, LLC, a contractor to NRC licensee Bradley Bastow, D.O., engaged in deliberate misconduct that caused Bradley D. Bastow, D. O. to be in violation of NRC requirements. Specifically, University Nuclear & Diagnostics, LLC, failed to calibrate a survey instrument yet provided falsified survey instrument calibration records dated August 13, 2010, and November 10, 2011; instructed its employees to document radiation survey results when the survey instrument was not working or not on site from October 5 to November 28, 2011, 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 from October 5 to November 28, 2011, and failed to perform an annual audit and falsified annual records on either October or November 24, 2011.

This is a Severity Level III violation (Section 6.9).

Pursuant to the provisions of 10 CFR 2.201, University Nuclear and Diagnostics is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-001, with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-13-026 and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from 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, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then you must 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 withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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 of Violation within two working days of receipt.

Dated this 13th day of May, 2014

required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at [http://www.nrc.gov/reading\\_rm/doc\\_collections/enforcement/actions/](http://www.nrc.gov/reading_rm/doc_collections/enforcement/actions/).

Sincerely,

*/RA/*

Cynthia D. Pederson  
Regional Administrator

Docket No. 150-00009  
License No. FL 4072-1

Enclosures:

1. NRC Investigation Result  
and Conclusions
2. Notice of Violation

cc w/encls: Mr. Philip Troy, Esq.  
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See next page

ADAMS Accession Number: ML14125A346

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- 1 FSME concurrence received via email from M. Burgess on April 22, 2014.
  - 2 OGC No Legal Objection received via email from C. Hair on April 30, 2014.
  - 3 OE concurrence received via email from T. Marenchin on April 29, 2014.

Letter to Avital Soffer from Cynthia D. Pederson dated May 13, 2014

SUBJECT: NOTICE OF VIOLATION – UNIVERSITY NUCLEAR & DIAGNOSTICS, LLC;  
NRC INSPECTION REPORT NO. 03035710/2012001(DNMS) AND  
INVESTIGATION REPORT NO. 3-2012-017

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