



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

November 6, 2014

EA-14-116

Bradley D. Bastow, D.O.
950 Blue Star Highway
Suite 1-2
South Haven, MI 49090

**SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$7,000; NRC FOLLOW-UP INSPECTION REPORT
NO. 03035710/2014001(DNMS) – BRADLEY D. BASTOW, D. O.**

Dear Dr. Bastow:

This letter refers to the inspections conducted on March 27, April 21, April 24, and May 5, 2014, at your facility in South Haven, Michigan, with continued in-office review through June 20, 2014. The purpose of the inspections were to verify compliance with the Confirmatory Order issued to you on September 3, 2013, and to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The purpose of the in-office review was to evaluate additional information not available during the onsite inspections. During the inspections, apparent violations of NRC requirements were identified. The significance of the issues and the need for lasting and effective corrective actions were discussed with you during a telephonic exit meeting that was held on July 1, 2014. Details regarding the apparent violations were provided 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>.

On September 19, 2014, a predecisional enforcement conference was conducted in the Region III office with you and your attorney to discuss the apparent violations, their significance, their root causes, and your corrective actions. A summary of the conference and a list of attendees was provided to you under a separate letter and is available in ADAMS at Accession Number ML14288A470. The slides you provided at the conference are available in ADAMS at Accession Number ML14279A552. The conference was transcribed, and a copy of the transcription is available in ADAMS at Accession Number ML14279A559.

During the conference, your attorney informed the NRC that you did not agree with the three issued Severity Level IV violations or with three of the apparent violations. With regard to the three apparent violations, your attorney stated that you believed that you had accompanied another radiation safety officer (RSO), that required documents had been posted, and that

weekly meetings with the nuclear medicine technologist had occurred, which should encompass the intent of quarterly meetings. The NRC requested that you provide additional information regarding the accompaniment of the RSO. On September 26, 2014, you provided a letter to address your accompaniment of an RSO and a second letter to request a license amendment placing your license in stand-by until you have completed corrective actions. These letters are available in ADAMS at Accession Number ML14279A119.

Based on the information developed during the inspection and the information that you provided during and after the conference, the NRC has determined that violations of NRC requirements occurred. The NRC carefully considered the information presented during the conference about documents being posted and quarterly meetings occurring. After further evaluation of all the information, including the information provided during the conference, the NRC determined that no violations existed for these examples. The remaining violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. Specifically, the NRC determined that you either did not meet the terms of your Confirmatory Order or did not meet them in the time specified by the Order. Of particular concern to the NRC was the failure to restore compliance to one of the initial violations that formed the basis of the Confirmatory Order – providing a calibrated and operable well counter or submitting a license amendment request for alternate instrumentation. Not having this instrumentation has a direct health and safety impact on your staff and patients in that, without the instrumentation, your staff are not able to provide accurate contamination readings.

The apparent cause of the current violations appeared to be similar to the cause of the violations that ultimately led to the Confirmatory Order – that your radiation safety officer is disengaged from his roles and responsibilities. The NRC license issued to Bradley D. Bastow, D. O. 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 its 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 Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a Severity Level III problem.

Because your facility has been the subject of escalated enforcement action within the last two years¹, 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.

¹ On September 3, 2013, the NRC issued a Confirmatory Order; Notice of Violation and a Civil Penalty to Bradley D. Bastow, D. O. for multiple safety violations of its license, including violations that had multiple examples.

The NRC determined that credit was not warranted for either *Identification* or *Corrective Action*. In regard to the *Identification* factor, the violations were identified by the NRC. In regard to *Corrective Action*, the NRC acknowledged that, following the NRC's March 27, 2014, inspection, you took actions to comply with the Confirmatory Order, although these actions were neither comprehensive nor complete. During the pre-decisional enforcement conference, your attorney described your corrective actions to come into compliance with NRC's regulations and to ensure that your staff remains in compliance. Particularly, your attorney noted that you had voluntarily stopped performing nuclear medicine activities under the license and that you would take action, prior to restarting your nuclear medicine program, to either replace the well counter or to submit a license amendment. Your attorney also stated that you were evaluating hiring a medical physicist to assume radiation safety officer responsibilities. However, the NRC noted the lack of firm commitments or dates in your response as to when the actions either were taken or would be taken. The NRC also considered that you had made previous commitments to come into compliance, but had failed to follow through to correct the violations. Finally, the NRC considered the information you provided following the conference about the qualifications of the individual shadowed as a radiation safety officer, obtaining a new radiation safety officer and, separately, requesting a license amendment to suspend your license until you completed the corrective actions.

Therefore, to emphasize the importance of prompt identification and comprehensive correction of violations and compliance with NRC requirements, after consultation with the Director, Office of Enforcement, I have been authorized to issue a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in twice the base amount of \$7,000 (Enclosure 1). In addition, issuance of this Notice constitutes escalated enforcement action that will subject you to increased inspection effort.

In regard to the Severity Level IV violations, in addition to discussing them during the conference, you provided a written response dated September 19, 2014, to the Notice of Violation included with Inspection Report No. 03035710/ 2014001(DNMS). Your letter stated that you were disputing two of the Severity Level IV violations and that you disagreed with the significance of the third. The NRC acknowledged receipt of your letter on October 9, 2014, (see ADAMS Accession Number ML14283A236), is currently evaluating the information you provided, and will address the disputed violations via separate correspondence when the NRC's evaluation is complete. The NRC has also processed your license amendment request and notified you on October 7, 2014, that your license was amended to limit the activities authorized (see ADAMS Accession Number ML14281A334).

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 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 continued compliance with regulatory requirements.

B. Bastow

-4-

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 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/

Cynthia D. Pederson
Regional Administrator

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

Enclosures:

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

cc w/encl 1: State of Michigan
Phillip Troy, Esquire

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Bradley D. Bastow, D. O.
South Haven, Michigan

License No.: 03035710
Docket No.: 21-32316-01
EA-14-116

During an NRC inspection conducted on March 27, April 21, April 24, and May 5, 2014, with continued review through June 20, 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:

In a Confirmatory Order issued on September 3, 2013, and published in the Federal Register on September 13, 2013, (78 FR 56745), the U.S. Nuclear Regulatory Commission modified Materials License 21-32316-01 to require Bradley D. Bastow, D. O. to take additional actions contained in Section V of the Order to address multiple NRC concerns identified during a special inspection on February 28 and April 3, 2012.

- A. Condition V.A.2 of the Confirmatory Order requires, in part, that the licensee will either restore a well counter to service (calibrated and operable) or will provide a license amendment request for alternate instrumentation within 60 days of the date of the order.

Contrary to the above, as of May 5, 2014, the licensee failed to restore a well counter to service (calibrated and operable) or to provide a license amendment request for alternative instrumentation. Specifically, on April 24, 2014, the licensee obtained a well counting instrument; however, the licensee did not have documentation or other evidence to confirm that the instrument had been calibrated and was operable for the detection and measurement of the radionuclide used by the licensee (technetium-99m).

- B. Condition V.B.1 of the Confirmatory Order requires that within 90 days of the date of the Order, Dr. Bastow will complete a medical RSO refresher training class.

Contrary to the above, as of December 13, 2013, Dr. Bastow failed to complete a medical RSO refresher training class within the required time period. Specifically, the licensee documented a series of on-line training modules that were not completed until March 21, 2014.

- C. Condition V.B.2 of the Confirmatory Order requires that, within 60 days of the completion of the RSO training identified in V.B.1, Dr. Bastow will meet with and "shadow" for at least 8 hours another RSO who oversees a nuclear medical program.

Contrary to the above, as of May 20, 2014, Dr. Bastow failed to meet with and "shadow" another RSO.

- D. Condition V.B.3 of the Confirmatory Order requires, in part, that the licensee provide a copy of the quarterly radiation safety program review reports to the NRC within 60 days of the completion of the audits. It further requires that the licensee must provide written certification that he has reviewed the radiation safety program review report and agrees with the results of the review along with independent observations that he has made of the health of the radiation safety program.

Contrary to the above:

1. From January 2014 through April 2014, the licensee failed to provide a copy of the quarterly radiation safety program review reports to the NRC within 60 days of the completion of the audits. Specifically, the licensee did not provide copies of the audits performed in November 2013 and January 2014 to the NRC until May 5, 2014.
2. As of May 5, 2014, the licensee failed to provide written certification with independent observation that he made of the health of the radiation safety program. Specifically, the licensee did not provide independent observations that were made of the health of the radiation safety program for the radiation safety program reviews performed in November 2013 and January 2014.

- E. Condition V.C.1 of the Confirmatory Order requires, in part, that, within 30 days of the date of the order, the licensee will document a written Safety Culture Policy that applies to all persons performing duties under the NRC license. The Policy must iterate that any concerned individuals can contact the NRC (provide phone number and contact person at NRC) for additional action on nuclear safety issues if necessary. It further requires that, within 30 days of the date of the Order, the licensee will provide a copy of the Safety Culture Policy to all persons (staff and contractors) performing duties under the NRC license and conspicuously post the policy or a notice about the policy in the licensee's office in at least two occasions.

Contrary to the above, as of May 5, 2014:

1. The licensee failed to have a Safety Culture Policy documented within 30 days of the Order that iterated that any concerned individuals can contact the NRC and that provided a phone number and contact person at the NRC. Specifically, the licensee developed and documented a Safety Culture Policy, dated October 22, 2013; however, the policy did not contain the specified information.
2. The licensee failed to provide a copy of the policy to the nuclear medicine technologist, the only person performing duties under the NRC license, and, until April 21, 2014, the licensee failed to post either the policy or a notice about the policy in the licensee's office.

- F. Condition V.C.2 of the Confirmatory Order requires, in part, that within 60 days of the date of the order, the RSO will provide initial training to the staff and contractors performing duties under the NRC license regarding safety culture and raising safety concerns and that the documentation of the training will be maintained for future inspection, including the dates of the training, the names of the attendees, and the subjects covered.

Contrary to the above, as of May 5, 2014, the licensee did not maintain documentation of initial training to staff and contractors performing duties under the NRC license regarding safety culture and raising safety concerns, including the dates of the training, the names of the attendees, and the subjects covered. Specifically, the licensee conducted initial training; however, the licensee did not document the dates of the training, the names of the attendees, and the subjects covered.

- G. Condition V.D.1 of the Confirmatory Order requires, in part, that the licensee ensure all documentation completed following issuance of the Order is complete, accurate, clear, and legible. If forms or documents contain signature blocks, the name of the signee will be printed or typed on the form and will include a date signed.

Condition V.B.3 of the Confirmatory Order requires, in part, that upon issuance of the order, the licensee will increase the radiation safety reviews to quarterly for one year.

Contrary to the above, as of March 27, 2014, the licensee failed to ensure that the quarterly radiation safety review completed on January 16, 2014 was complete and accurate. Specifically:

1. The RSO signature block on the summary letter was not signed or dated;
2. The Dose Calibrator Evaluation section indicated that the linearity check was performed on January 16, 2014, using the CaliCheck method; however, the linearity check was actually performed on January 20, 2014, through February 11, 2014, using the decay method;
3. The Personnel Dosimetry Report indicated ALARA exposure action levels for extremity dosimeters of 1875 mrem per quarter for Level 1 and 5625 mrem per quarter for Level 2 with no action taken, when both the license application dated April 26, 2011, and documentation posted at the facility indicated action levels of 1250 mrem for Level 1 and 3750 mrem for Level 2;
4. The Survey Meter Status Report did not include the licensee's back-up survey meter, serial number 173094;
5. The RSO signature blocks on the Dose Calibrator Evaluation and on the dose calibrator linearity tests did not include a date signed.

- H. Condition V.E of the Confirmatory Order requires that, unless otherwise specified, the licensee will submit notification to the NRC upon completion of each specific action at six months, one year, and annually thereafter until total completion.

Contrary to the above, as of May 5, 2014, the licensee had not submitted notification to the NRC upon completion of each specific action at six months.

This is a Severity Level III problem (Section 6.3).
Civil Penalty – \$7,000

Pursuant to the provisions of 10 CFR 2.201, Bradley D. Bastow (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a copy to the Document Control Desk, Washington, DC 20555-0001, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation (EA-14-116)" and should include for each alleged 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. If an adequate reply is not received within the time specified in this Notice, the NRC may issue an order or a Demand for Information requiring you to explain why your license should not be modified, suspended, or revoked or why the NRC should not take other action as may be proper. Consideration may be given to extending the response time for good cause shown.

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, 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 6th day of November, 2014.

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 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/

Cynthia D. Pederson
Regional Administrator

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

Enclosures:

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

cc w/encl 1: State of Michigan
Phillip Troy, Esquire

DISTRIBUTION w/ Encl 1

RIDSSECYMAILCENTER

OCADistribution

Mark Satorius

Roy Zimmerman

Patricia Holahan

Shahram Ghasemian

Thomas Marenchin

Cynthia Pederson

Darrell Roberts

Marvin Itzkowitz

Catherine Scott

Christopher Hair

Catherine Haney

Pamela Henderson

Michele Burgess

Robert Sun

Brice Bickett

David Gamberoni

Vivian Campbell

Holly Harrington

Hubert Bell

Cheryl McCrary

Barbara Gusack

David D'Abate

F. Paul Paduzzi

Patrick Louden

Julio Lara

Aaron McCraw

MIB Inspectors

Steven Orth

Allan Barker

Harral Logaras

James Lynch

Viktoria Mitlyng

Prema Chandrathil

Patricia Lougheed

Paul Pelke

Magdalena Gryglak

Sarah Bakhsh

Carmen Olteanu

RidsOemailCenter

OEWEB Resource

See previous concurrences

FILE NAME: EA-14-116 Bastow draft final action.docx

OFFICE	RIII	RIII	RIII	RIII	D:NMSS	D:OGC	D:OE	RIII	RIII
NAME	Lougheed	McCraw	Louden	Roth	Henderson ¹ Burgess	Scott ² Hair	Holahan ³ Marenchin	Orth	Pederson
DATE	10/15/14	10/16/14	10/19/14	10/21/14	10/30/14	10/28/14	10/31/14	11/04/14	11/04/14

OFFICIAL RECORD COPY

¹ NMSS concurrence provided via e-mail from M. Burgess via T. Marenchin on October 30, 2014

² OGC 'no legal objection' and concurrence provided via e-mail from C. Hair on October 28, 2014

³ OE concurrence provided via e-mail from T. Marenchin on October 31, 2014