



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

August 4, 2015

IA-14-039

Bradley D. Bastow, D. O.
[HOME ADDRESS DELETED
UNDER 10 CFR 2.390]

SUBJECT: CONFIRMATORY ORDER TO DR. BRADLEY D. BASTOW, D. O.

Dear Dr. Bastow:

The enclosed Confirmatory Order is being issued to you based on discussions with you on September 23 and October 23, 2014. On September 19, 2014, you participated in a Predecisional Enforcement Conference to discuss apparent violations of NRC requirements identified during a recent NRC inspection at your facility. The apparent violations, in part, appeared to stem from your performance as the radiation safety officer. Subsequent to the conference, you responded to the NRC by letter dated September 19, 2014, and provided the NRC a commitment that you would remove yourself as the radiation safety officer on license No. 21-32316-01 and would appoint another individual as the radiation safety officer before requesting to resume routine licensed activities.

On November 6, 2014, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty – \$7,000. This letter provided the outcome of NRC's inspection documented in 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 and the final letter is available in ADAMS at Accession Number ML14309A590. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC has also reviewed your response to the Notice of Violation and Proposed Imposition of Civil Penalty, provided on December 6, 2014 (ML15035A562). On August 4, 2015, the NRC issued a Civil Penalty Imposition Order (ML15181A222).

During the enforcement conference and subsequent to it, the NRC expressed reservations about your ability to devote sufficient time and effort to performing your duties as radiation safety officer for your NRC radioactive materials license. The NRC considers it essential for licensees to have a radiation safety officer devoted to ensuring that radioactive materials are used safely, securely, and in compliance with the applicable requirements. The continued non-compliances have resulted in our lack of confidence in your capacity as a radiation safety officer.

In light of your agreement to a restriction as a radiation safety officer or assistant radiation safety officer, the NRC is satisfied that its concerns will be addressed by memorializing your commitments in a Confirmatory Order (Enclosure 1). As evidenced by your signed "Consent and Hearing Waiver Form" (Enclosure 2), dated April 17, 2015, you agreed to the issuance of the Confirmatory Order.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Confirmatory Order shall be subject to criminal prosecution, as set forth in that section. Violation of this Confirmatory Order may also subject the person to civil monetary penalties.

In accordance with Title 10 of the *Code of Federal Regulations*, Section 2.390 of the NRC's "Rules of Practice," a copy of this letter, along with its enclosures, will be made available electronically for public inspection in the NRC Public Document Room or from ADAMS. The Confirmatory Order will be published in the Federal Register. The NRC also publishes Confirmatory Orders on its Web site under Significant Enforcement Actions at <http://www.nrc.gov/about-nrc/regulatory/enforcement.html>.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of

Bradley D. Bastow, D. O.

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IA-14-039

CONFIRMATORY ORDER

I

Bradley D. Bastow, D. O., (licensee) is the holder of Materials License No. 21-32316-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30 on April 20, 2001, and renewed on December 7, 2011. The license authorizes the operation of Bradley D. Bastow, D. O., at his place of business (Cardiology II, P.C.), in accordance with conditions specified therein. It further specifies that the radiation safety officer (RSO) for the license will be Bradley D. Bastow, D. O. (Dr. Bastow). The licensee's facility is located in South Haven, Michigan.

This Confirmatory Order is the result of an agreement reached with Dr. Bastow during discussions on September 23 and October 23, 2014.

II

On February 28, and April 3, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at the licensee's facility in South Haven, Michigan, with continued in-office review through May 24, 2012. The NRC Office of Investigations (OI) began an investigation on April 2, 2012, into several of the issues identified during the inspection. OI completed its investigation on January 31, 2013. The details of the inspection were documented in NRC Inspection Report No. 03035710/2012001(DNMS) issued on December 19, 2012, and the results of the OI investigation were documented in a letter dated April 18, 2013, which identified

Enclosure 1

14 apparent violations. The April 18, 2013, letter offered the licensee the opportunity to provide a written response, attend a predecisional enforcement conference, or attend an alternative dispute resolution (ADR) session.

One apparent violation identified by the NRC involved the RSO's (i.e., Dr. Bastow's) failure to ensure radiation safety activities were conducted in accordance with licensee-approved procedures and regulatory requirements. Specifically, the NRC identified several radiation safety violations, including the failure to conduct radiation surveys, calibrate radiation detection instrumentation, provide and process radiation monitoring devices to individuals, and conduct source leak tests and inventories. These apparent violations occurred, in part, due to Dr. Bastow not performing his duties as the RSO.

On July 1, 2013, the licensee and the NRC met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. ADR is a process in which a neutral mediator with no decision-making authority assists the parties in reaching an agreement on resolving any differences regarding the dispute. At the ADR session, a preliminary agreement was reached and, on September 3, 2013, a Confirmatory Order (EA-13-025) was issued to Bradley D. Bastow, D. O., as the licensee.

On March 27, April 21, April 24, and May 5, 2014, the NRC performed inspections at the licensee's facility in South Haven, Michigan, in part, to verify compliance with the Confirmatory Order issued on September 3, 2013. The NRC also performed continued in-office review through June 20, 2014, to evaluate additional information not available during the onsite inspections. During the inspections, apparent violations of NRC requirements were identified, including a number of apparent violations of the Confirmatory Order. On July 30, 2014, the NRC provided the licensee with an inspection report detailing the results of the inspection. In

the accompanying cover letter, the NRC requested that the licensee attend a Predecisional Enforcement Conference (PEC) to discuss the inspection results.

The NRC identified violations of the Confirmatory Order that were attributable to Dr. Bastow's activities as the RSO. For example, the violations involved the failure to repair or replace radiation detection instrumentation and to ensure that the instrumentation was calibrated and operable, the failure to shadow a radiation safety officer, and the failure to maintain complete and accurate documents. The violations continued to indicate that Dr. Bastow was not adequately fulfilling his duties as the RSO.

On September 19, 2014, the licensee, its attorney and the NRC met in a transcribed PEC. During the meeting, the licensee's attorney described the corrective actions taken and the issues where the licensee disagreed with the NRC's conclusions. Based on information gathered during the inspections and information provided during and after the PEC, the NRC made a determination that a Severity Level III problem existed and issued a Notice of Violation and Proposed Imposition of Civil Penalty to Bradley D. Bastow, D. O. (licensee) on November 6, 2014.

In a letter dated, September 19, 2014 (ML14279A119), Dr. Bastow requested that the facility's license be amended to standby status and that no activities involving nuclear stress testing will be conducted. On October 7, 2014, the NRC amended the license to possession and storage in standby.

III

Following the PEC, on September 23, 2014, during a telephone call with the NRC, the licensee's attorney agreed that Dr. Bastow would commit to no longer being RSO. This statement was confirmed in a letter from the licensee dated September 19, 2014, and received by the NRC on September 26, 2014 (ML14279A119).

On October 23, 2014, during a telephone call with the NRC, Dr. Bastow verbally agreed with the issuance of a Confirmatory Order to articulate that commitment. On April 17, 2015, Dr. Bastow consented to issuing this Confirmatory Order with the commitments, as described in Section V below. Dr. Bastow further agreed that this Confirmatory Order is to be effective 30 days after issuance and that he has waived his right to a hearing.

IV

Since the individual has agreed to take additional actions to address NRC concerns, as set forth in Section III above, the NRC has concluded that its concerns can be resolved through issuance of this Confirmatory Order.

I find that Dr. Bastow's commitments as set forth in Section V are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that Dr. Bastow's commitments be confirmed by this Confirmatory Order. Based on the above and Dr. Bastow's consent, this Confirmatory Order is effective 30 days after issuance of the Confirmatory Order.

Accordingly, pursuant to Sections 81,161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED THAT:

1. Beginning on the effective date of this Order (i.e., September 3, 2015), Dr. Bastow is prohibited from serving as an RSO, including an assistant or associate RSO, while in NRC jurisdiction. This includes working as an RSO; being listed as an RSO on a license; and performing any RSO duties for any licensee while in NRC jurisdiction, including activities under an Agreement State license while working under reciprocity. This prohibition does not prevent Dr. Bastow from serving as an authorized user.
2. No later than the effective date of this Order, Dr. Bastow must:
 - a. Inform the NRC, in writing, that he is not listed as RSO (or assistant or associate RSO) on any license (other than 21-32316-01).

OR

- b. If Dr. Bastow is currently involved with any licensee (other than license 21-32316-01) in NRC-licensed activities as an RSO or assistant or associate RSO:

- (1) Provide a copy of this Order to that licensee, and remind them of their obligation to obtain a new RSO and amend their NRC license to replace Dr. Bastow as RSO and
 - (2) Provide, in writing, to the NRC, the license number, licensee name, address and telephone number, of each licensee.
3. Prior to returning license 21-32316-01 to active status, Dr. Bastow will identify a new individual to replace Dr. Bastow as RSO and inform the NRC in writing by submitting a license amendment request.
4. At any time after the effective date of this Order, Dr. Bastow may file a written request with the NRC that this Order be rescinded, such that he could again serve as an RSO in NRC jurisdiction. Such a request shall include the following:
 - a. Dr. Bastow will provide written documentation of satisfactory completion of an in-person 40-hour medical RSO training class.
 - (1) The training class completion date will be after the effective date of this Order;
 - (2) The written documentation will include completion date, provider name and contact information, instructor name, and class agenda/outline;
 - (3) The documentation must demonstrate that the training covered the following topics: (a) radiation physics and instrumentation; (b) radiation

protection; (c) mathematics pertaining to the use and measurement of radioactivity; (d) radiation biology; and e) radiation dosimetry.

b. Dr. Bastow will provide written documentation that he met with and observed (i.e., “shadowed”) an RSO who oversees a nuclear medical program for a minimum of 24 working hours (3 working days).

- (1) The completion date will be after the effective date of this Order.
- (2) The “shadowing” effort must, at a minimum, cover the following topics via observation or discussion with the RSO:
 - (a) Shipping, receiving, and performing related radiation surveys;
 - (b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
 - (c) Securing and controlling byproduct material;
 - (d) Using administrative controls to avoid mistakes in the administration of byproduct material;
 - (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
 - (f) Using emergency procedures to control byproduct material; and
 - (g) Disposing of byproduct material.
- (3) The written documentation must include a letter written, dated, and signed by the “shadowed” RSO that:

- (a) Confirms that the “shadowed” RSO was, for the entire “shadow” period, listed as an RSO for an NRC or Agreement State medical use license and had oversight of a medical use program authorized for 35.100 and 35.200; and lists the license number;
 - (b) Confirms all topics from Item b.2 above were covered and satisfactorily completed during the effort, and provides the approximate number of hours spent on each topic;
 - (c) Attests to the “shadowed” RSO’s assessment of Dr. Bastow’s competency to function independently as an RSO for a medical use license for 35.100 and 35.200 medical uses.
 - (d) The written documentation will include a statement written, dated, and signed by Dr. Bastow articulating the insights that he gained by the effort.
- c. Dr. Bastow shall provide the NRC with a written document describing in detail his understanding of his requirements and responsibilities as an RSO and containing his acknowledgment of these requirements and responsibilities. This document will include a statement of Dr. Bastow’s commitment to compliance with regulatory requirements, including providing complete and accurate information, and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.
- 5. All information provided to NRC pursuant to this section shall be provided in writing and addressed and mailed to Cynthia D. Pederson, Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, with a copy also mailed to Dr. Patricia

K. Holahan, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission,
Washington, DC 20555-0001.

6. This Order shall be effective 30 days (i.e., September 3, 2015), after issuance and shall remain in effect until the conditions specified above have been met and the NRC determines, in writing, that the Order is rescinded.

VI

Any person adversely affected by this Confirmatory Order, other than Dr. Bastow, may request a hearing within 30 days of the issuance date of this Confirmatory Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made, in writing, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-001, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's e-filing rule (72 FR 49139; August 28, 2007), as amended by 77 FR 46562; August 3, 2012, (codified in pertinent part at 10 CFR Part 2, Subpart C). The e-filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of e-filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to: (1) request a digital (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the e-submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. System requirements for accessing the e-submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's e-filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the e-filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange (EIE), users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene through the EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's e-filing system. To be timely, an electronic filing must be submitted to the e-filing system no later than 11:59 p.m. Eastern Time (ET) on the due date. Upon receipt of a transmission, the e-filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The e-filing system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/ petition to intervene is filed so that they can obtain access to the document via the e-filing system.

A person filing electronically using the NRC's adjudicatory e-filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail at MSHD.Resource@nrc.gov, or by a toll-free call at (866) 672-7640. The NRC Meta System Help Desk is available between 8:00 a.m. and 8:00 p.m., ET, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their

initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first-class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using e-filing, may require a participant or party to use e-filing if the presiding officer subsequently determines that the reason for granting the exemption from use of e-filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, participants are requested not to include copyrighted materials in their submission, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application.

If a person other than Dr. Bastow requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue a separate Order designating the time and place of any hearings, as appropriate. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be effective and final 30 days after issuance of the Confirmatory Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

Dated at Lisle, Illinois this 4th day of August, 2015

For the Nuclear Regulatory Commission

/RA/

Cynthia D. Pederson
Regional Administrator

CONSENT AND HEARING WAIVER FORM

I, Dr. Bradley D. Bastow, hereby agree to comply with the terms and conditions of the Confirmatory Order arising out of a predecisional enforcement conference conducted on September 19, 2014, and my letter dated September 19, 2014. I understand that I may not perform the duties of a Radiation Safety Officer under any license in NRC jurisdiction until the terms of this Order have been met. I understand that the Confirmatory Order will become effective 30 days after its issuance. By signing below, I consent to the issuance of the referenced Confirmatory Order, effective 30 days after being issued, and, by doing so, agree to waive the right to request a hearing on all or any part of the Confirmatory Order.



Dr. Bradley D. Bastow, D.O.
Radiation Safety Officer
Bradley D. Bastow, D.O.


Date

Last Revised or Reviewed – October 2010

Enclosure 2

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Confirmatory Order shall be subject to criminal prosecution, as set forth in that section. Violation of this Confirmatory Order may also subject the person to civil monetary penalties.

In accordance with Title 10 of the *Code of Federal Regulations*, Section 2.390 of the NRC's "Rules of Practice," a copy of this letter, along with its enclosures, will be made available electronically for public inspection in the NRC Public Document Room or from ADAMS. The Confirmatory Order will be published in the Federal Register. The NRC also publishes Confirmatory Orders on its Web site under Significant Enforcement Actions at <http://www.nrc.gov/about-nrc/regulatory/enforcement.html>.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Enclosures:

1. Confirmatory Order
2. Consent and Hearing Waiver

DISTRIBUTION w/Encl

See next page

*See previous concurrence

ADAMS Accession Number ML15223B103

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DATE	3/6/15	3/10/15	3/19/15	3/20/15	
OFFICE	NMSS	OGC	OE	RIII	RIII
NAME	Wray ¹	Hair ²	Wray ³	Skokowski	Pederson
DATE	07/31/15	07/31/15	07/31/15	08/04/15	08/04/15

OFFICIAL RECORD COPY

¹ NMSS concurrence provided via email from J. Wray on July 31, 2015

² OGC concurrence provided via email from C. Hair on July 31, 2015

³ OE concurrence provided via email from J. Wray on July 31, 2015

Letter to Bradley D. Bastow, D. O. from Ms. Cynthia D. Pederson dated August 4, 2015

SUBJECT: CONFIRMATORY ORDER TO DR. BRADLEY D. BASTOW, D. O.

DISTRIBUTION w/ Enclosures

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