



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

Region III  
2443 Warrenville Road, Suite 210  
Lisle IL 60532-4352

September 3, 2013

EA-13-025

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

**SUBJECT: CONFIRMATORY ORDER; NOTICE OF VIOLATION AND CIVIL PENALTY – \$1,000, NRC INSPECTION REPORT NO. 03035710/2012001 AND OFFICE OF INVESTIGATIONS REPORT NO. 3-2012-017; BRADLEY D. BASTOW, D. O.**

Dear Dr. Bastow:

The enclosed Confirmatory Order is being issued to Bradley D. Bastow, D. O., as a result of a successful Alternative Dispute Resolution (ADR) session. The enclosed commitments were made by you, as the licensee, as part of a settlement agreement between you and the U.S. Nuclear Regulatory Commission (NRC) concerning apparent violations of NRC requirements as discussed in the enclosure to our letter dated April 18, 2013.

Our April 18, 2013, letter provided you with the results of an investigation conducted by the NRC's Office of Investigations, to review the actions of your contractor, University Nuclear and Diagnostics, and the Radiation Safety Officer for NRC license No. 21-21-32316-01 in carrying out the requirements of the radiation safety program. The NRC identified a number of apparent violations of NRC requirements as documented in our April 18, 2013, letter. Our letter also informed you that the apparent violations were being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy and provided you with the option of: (1) providing a written response to the violations; (2) attending a Predecisional Enforcement Conference; or (3) requesting ADR with the NRC in an attempt to resolve any disagreement regarding whether violations occurred, the appropriate enforcement action, and the appropriate corrective actions.

In response to our letter, you requested ADR. An ADR mediation session was held on July 1, 2013, and a preliminary settlement agreement was reached. The elements of the preliminary agreement were formulated and agreed to at the mediation session. Consistent with the purposes of ADR, you and the NRC acknowledged that the session was not for the purposes of reaching any conclusions regarding any facts or circumstances as discussed in our letter dated April 18, 2013.

At the session, you agreed that a Confirmatory Order and a Notice of Violation would be issued in settlement of a disputed claim in order to avoid further action by the NRC. In addition, you agreed to pay a civil penalty in the amount of \$1,000 as part of the settlement. In light of the corrective actions you have taken or agreed to take, as described in the Confirmatory Order (Enclosure 1) and Notice of Violation (Enclosure 2), the NRC is satisfied that its concerns will be addressed by making your commitments legally binding. Therefore, the NRC has agreed not to pursue any further enforcement action in connection with the issues described in our letter dated April 18, 2013.

As evidenced by your signed "Consent and Hearing Waiver Form" (Enclosure 3) dated August 22, 2013, 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 10 CFR 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 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>. 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

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

Enclosures:

1. Confirmatory Order
2. Notice of Violation
3. Consent and Hearing Waiver

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-35710
Bradley D. Bastow, D. O.	)	License No. 21-32316-01
South Haven, Michigan	)	EA-13-025

CONFIRMATORY ORDER MODIFYING LICENSE

I

Bradley D. Bastow, D. O., (Dr. Bastow or the licensee) is the holder of Materials License No. 21-32316-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 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.) (facility) in accordance with conditions specified therein. The facility is located on the licensee's site in South Haven, Michigan.

This Confirmatory Order is the result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on July 1, 2013.

II

On February 28, and April 3, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at the Bradley D. Bastow, D. O., facility in South Haven, Michigan, with continued in-office review through May 24, 2012. The details of the inspection were documented in NRC Inspection Report No. 03035710/2012001(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 several of the issues. OI completed its investigation on January 31, 2013.

During the inspection and investigation, the NRC determined that Bradley D. Bastow, D. O., was in apparent violation of NRC requirements by: (1) failing to perform weekly contamination surveys; (2) failing to perform storage area surveys; (3) failing to conduct a survey instrument calibration; (4) failing to monitor the external surfaces of labeled packages for radioactive contamination; (5) failing to conduct dose calibrator linearity tests that were calibrated with nationally recognized standards; (6) failing to conduct a formal annual review of the radiation safety program; (7) failing to ensure that records were complete and accurate; (8) failing to issue a whole body radiation exposure measuring device to an individual who was occupationally exposed to ionizing photon radiation on a regular basis and failing to issue a finger radiation exposure measuring device to an individual who handled radioactive material on a regular basis; (9) failing to read film badges on a monthly basis, and the named Radiation Safety Officer (RSO) failing to evaluate the results; (10) failing to leak test sealed sources at 6 months intervals; (11) failing to conduct a semi-annual physical inventory of all sealed sources in its possession; (12) failing to perform daily surveys; (13) failing to assay wipes for removable contamination using a procedure sufficiently sensitive to detect 2000 disintegrations per minute (dpm); and (14) the named RSO failing to ensure that radiation safety activities were being performed in accordance with licensee-approved procedures and regulatory requirements.

On July 1, 2013, Bradley D. Bastow, D. O., 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. This confirmatory order is issued pursuant to the agreement reached during the ADR process.

### III

In response to the NRC's offer, Bradley D. Bastow, D. O., requested use of the NRC ADR process to resolve differences it had with the NRC. During that ADR session, a preliminary settlement agreement was reached. The elements of the agreement consisted of the following:

A. Restoring Compliance:

A.1. The NRC will issue a written Notice of Violation to accompany the Order addressing the violations and the licensee will respond with how the violations were corrected, within 30 days of the date of the Order. The NRC agrees to group the violations to reduce the total number such that all the completeness and accuracy violations are discussed in one violation and all the survey violations are discussed in a second violation.

A.2. Within 30 days of the date of the Order, the licensee will ensure that all equipment listed on the license (except the well counter) is restored to service, calibrated, and operable, including a back-up survey meter. In the case of the well counter, 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.

B. RSO responsibilities and involvement:

- B.1 Within 90 days of the date of the Order, Dr. Bastow will complete a medical RSO refresher training class (approximately 8 hours).
- B.2 Within 60 days of completion of the RSO training identified in B.1, Dr. Bastow will meet with and “shadow” for at least 8 hours another RSO who oversees a nuclear medical program. The licensee will retain documentation showing the name of the RSO whom he shadowed, contact information, approximate hours spent and insights gained. If Dr. Bastow is unable to shadow another RSO, then the licensee will document the names and contact information for three individuals whom he contacted, the dates of contact and the reasons they provided for not allowing him to shadow them.
- B.3 Upon issuance of the Order, the licensee will increase radiation safety program reviews from annually to quarterly for one year and provide a copy of the reports to the NRC within 60 days of completion of the audits. The reports must include all documented safety concerns raised by persons (staff and contractors) performing duties under the NRC license, along with any self-identified violations and the corrective actions taken to resolve the concerns. After the first year, the licensee will provide its annual written report to the NRC for the next three years. The reviews will be conducted by an independent consultant under contract with the licensee. The licensee must provide written certification that he has reviewed the 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; the

licensee will also implement actions recommended in the report or document justification for not implementing the recommended actions.

C. Safety Culture:

C.1. Within 30 days of the date of the Order, the licensee will document a written Safety Culture Policy that applies to all persons (staff and contractors) performing duties under the NRC license. The policy must include that concerns will be documented, the actions taken to resolve the concerns, who resolved the concern, and when the concern was resolved. Upon resolution of the concern, the documented concern is signed by both the concerned individual and the RSO that resolution was satisfactory. If the concern cannot be resolved, the documented concern should state why the concern cannot be resolved and the concerned individual understands why the concern cannot be resolved. The Safety Culture Policy must iterate that any concerned individual can contact the NRC (provide phone number and contact person at NRC) for additional action on nuclear safety issues if necessary. The licensee shall provide a copy of the 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 several locations.

C.2. 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. For the next two years, the RSO will provide annual refresher training. The RSO will provide training to any new staff or contractors performing duties under the NRC license within 30 days of their

arrival. 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.

C.3. Once a quarter beginning within 60 days of the date of the Order, the licensee will meet with each person (staff and contractors) performing duties under the NRC license to solicit concerns and will document any concerns and the actions taken to address them. This shall continue for at least three years. The results shall be documented in the quarterly or annual audit.

D. Accuracy and Completeness of Records:

D.1 Within 90 days of the date of the Order, the licensee will review its records for 2012 and 2013 against NRC requirements and license commitments. The licensee will verify that all required records (including all records and documents created in support of such records) are onsite and are available for inspection. Furthermore, the licensee shall ensure that any supporting worksheets are clearly attached. The licensee shall ensure all documentation is complete, accurate, clear, and legible and information is easily traceable from one form to another without question. For example, survey instrumentation shall clearly indicate model and serial numbers. 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. This review shall be completed within 90 days of the date of the Order. Any discrepancies will be documented and the NRC informed within the following 30 days.



D.2 The NRC agrees to waive any additional enforcement action for any additional examples of the violations described above identified as a result of the reconciliation effort identified in D.1.

E. Notification of Completion of Activities:

Unless otherwise specified, the licensee will submit written notification to:

U.S. NRC Region III  
Director, Division of Nuclear Material Safety  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

upon completion of each specific action at six months, one year, and annually thereafter until total completion.

F. The resulting Confirmatory Order will be considered an escalated enforcement action by the NRC for any future assessment of Bradley D. Bastow, D. O., as appropriate.

G. In consideration of the commitments above, the NRC agrees to a civil penalty in the amount of \$1,000 and to take no further enforcement action in the matter of EA-13-025 discussed in the NRC's letter to Dr. Bastow dated April 18, 2013.

On August 22, 2013, Bradley D. Bastow, D. O., consented to issuing this Order with the commitments, as described in Section V below. Bradley D. Bastow, D. O., further agreed that

this Order is to be effective upon issuance and that the licensee has waived its right to a hearing.

#### IV

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

I find that Bradley D. Bastow, D. O.'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 Bradley D. Bastow, D. O.'s commitments be confirmed by this Order. Based on the above and Bradley D. Bastow, D. O.'s consent, this Confirmatory Order is effective upon issuance.

#### V

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 LICENSE NO. 21-32316-01 IS MODIFIED AS FOLLOWS:

A. Restoring Compliance:

A.1. Within 30 days of the date of the Order, the licensee will respond with how the violations enclosed with the Order were corrected.

A.2. Within 30 days of the date of the Order, the licensee will ensure that all equipment listed on the license (except the well counter) is restored to service, calibrated, and operable, including a back-up survey meter. In the case of the well counter, 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.

B. RSO responsibilities and involvement:

B.1 Within 90 days of the date of the Order, Dr. Bastow will complete a medical RSO refresher training class (approximately 8 hours).

B.2. Within 60 days of completion of the RSO training identified in B.1, Dr. Bastow will meet with and “shadow” for at least 8 hours another RSO who oversees a nuclear medical program. The licensee will retain documentation showing the name of the RSO whom he shadowed, contact information, approximate hours spent and insights gained. If Dr. Bastow is unable to shadow another RSO, then the licensee will document the names and contact information for three individuals whom he contacted, the dates of contact, and the reasons they provided for not allowing him to shadow them.

B.3. Upon issuance of the Order, the licensee will increase radiation safety program reviews from annually to quarterly for one year, and provide a copy of the reports to the NRC within 60 days of completion of the reviews. The reports must include all documented safety concerns raised by persons (staff and contractors) performing duties under the NRC license, along with any self-identified violations and the corrective actions taken to resolve the concerns. After the first year, the licensee will provide its annual written report to the NRC for the next three years. The reviews will be conducted by an independent consultant under contract with the licensee. The licensee must provide written certification that he has reviewed the 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; the licensee will also implement actions recommended in the report or document justification for not implementing the recommended actions.

C. Safety Culture:

C.1. Within 30 days of the date of the Order, the licensee will document a written Safety Culture Policy that applies to all persons (staff and contractors) performing duties under the NRC license. The policy must include that all concerns will be documented, the actions to be taken by the licensee to resolve the concerns, which individual will be responsible for the resolution of the concerns, and the expected timeframe in which the concern will be resolved. Upon resolution of the concern, the documented concern is signed by both the concerned individual and the RSO that resolution was satisfactory. If the concern cannot be resolved, the documented concern should state why the concern cannot be resolved and that the concerned individual understands why the concern cannot be resolved. The

Safety Culture Policy must iterate that any concerned individual can contact the NRC (provide phone number and contact person at NRC) for additional action on nuclear safety issues if necessary. The licensee shall provide a copy of the 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 locations.

C.2. 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. For the next two years, the RSO will provide annual refresher training. The RSO will provide training to any new staff or contractors performing duties under the NRC license within 30 days of their arrival. 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.

C.3. Once a quarter beginning within 60 days of the date of the Order, the licensee will meet with each person (staff and contractors) performing duties under the NRC license to solicit concerns and will document any concerns and the actions taken to address them. This shall continue for at least three years. The results shall be documented in the quarterly or annual audit.

D. Accuracy and Completeness of Records:

D.1 Within 90 days of the date of the Order, the licensee will review its records for 2012 and 2013 against NRC requirements and license commitments. The

licensee will verify that all required records (including all records and documents created in support of such records) are onsite and are available for inspection. Furthermore, the licensee shall ensure that any supporting worksheets are clearly attached. This review shall be completed within 90 days of the date of the Order. Any discrepancies will be documented and the NRC informed within the following 30 days.

The licensee shall ensure all documentation completed following issuance of the Order is complete, accurate, clear, and legible. For example, survey instrumentation shall clearly indicate model and serial numbers. 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.

E. Notification of Completion of Activities:

Unless otherwise specified, the licensee will submit written notification to:

U.S. NRC Region III  
Director, Division of Nuclear Material Safety  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

upon completion of each specific action at six months, one year, and annually thereafter until total completion.

- F. Within 30 days of the date of the Order, the licensee shall pay the civil penalty in the amount of \$1,000 in accordance with NUREG/BR-0254 and submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, a statement indicating when and by what method payment was made.

The Regional Administrator, Region III, may, in writing, relax or rescind any of the above conditions upon demonstration by Bradley D. Bastow, D. O., of good cause.

## VI

Any person adversely affected by this Confirmatory Order, other than Bradley D. Bastow, D. O., may request a hearing within 20 days of its publication in the Federal Register. 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, 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 E-Filing rule (72 FR 49139, August 28, 2007). 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 ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by email at [hearing.docket@nrc.gov](mailto:hearing.docket@nrc.gov), or by telephone at (301) 415-1677, to request: (1) 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/apply-certificates.html>. System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site 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 on the NRC's public Web site 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. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site 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 on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC 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, applicants and other participants (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 agency'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 Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by email at [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov), or by a toll-free call at (866) 672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, 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 NRC's electronic hearing docket which is available to the public at [http://ehd.nrc.gov/EHD\\_Proceeding/home.asp](http://ehd.nrc.gov/EHD_Proceeding/home.asp), 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, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person other than the licensee 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 C.F.R. 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an order designating the time and place of any hearing. 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 final 20 days from the date this Confirmatory Order is published in the Federal Register 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.

A REQUEST FOR HEARING SHALL NOT STAY THE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY  
COMMISSION

*/RA/*

Cynthia D. Pederson  
Regional Administrator  
Region III

Dated this 3<sup>rd</sup> day of September 2013

## NOTICE OF VIOLATION

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

Docket No. 030-35710  
License No. 21-32316-01  
EA-13-025

- A. Title 10 of the Code of Federal Regulations (10 CFR) 30.9, "Completeness and Accuracy of Information," item (a) requires, in part, that information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the licensee shall be complete and accurate in all material respects.

Contrary to the above, the following examples of incomplete or inaccurate records were identified:

1. The survey instrument calibration record dated November 10, 2011, was inaccurate. The calibration source used had insufficient strength to provide the recorded reading for the high end and the explanation given (that there was high background radiation) would render the low end readings inaccurate. The calibration data was identical to that from 2010, which was implausible.
2. Dose calibrator linearity tests dated June 15, 2010, October 25, 2010, January 25, 2011, April 25, 2011, August 5, 2011, November 30, 2011, and March 5, 2012, were inaccurate as they used different calibration factors each time although the licensee's contract consultant only owned two sets of CaliCheck sleeves and all of the calibrations were done by the licensee's contract consultant. Neither the licensee nor the contract consultant was able to provide consistent calibration factors or an explanation for the results.
3. An annual audit report dated November 30, 2011, was signed by the radiation safety officer. The audit was also incomplete in that it was not signed by the person performing the audit. Additionally, the audit report contains factual errors such as stating that the licensee held a State of Florida license and that the most recent State inspection was reviewed when the NRC conducts inspections rather than the State of Michigan.
4. The ALARA audit checklist dated October 24, 2011, was inaccurate in that it listed the serial number of a survey meter that neither the licensee nor its contract consultant owned. It was also incomplete in that it was not signed by the radiation safety officer, although it had a block for the radiation safety officer to sign.
5. From approximately June 2010 until October 25, 2011, records of package surveys and weekly surveys were not accurate in that they were recorded in counts per minute rather than the disintegrations per minute (dpm) required by the form. After October 25, 2011, the form was changed to state that counts per minute were being recorded; however, this continued to be inaccurate as the license required the results to be recorded as dpm per square centimeter.

6. Survey records for October 5, 10, 11, 17, 24, 25, and 31, November 1, 7, 8, 14, 15, 21, and 22, 2011, were inaccurate as they listed the serial number of a survey meter that neither the licensee nor its contract consultant owned. The survey record for October 10 also was dated 2010, although the attached dose slips were for 2011. Survey records for October 18, December 13 and 14, 2011, were incomplete as they did not contain the serial number of the survey meter used to record the data.
  7. Storage record surveys dated January 25, 2011, and November 30, 2011, were not accurate. Specifically, the person who signed the surveys was not on site on the dates indicated on the surveys. The actual dates when the surveys were performed were unable to be verified, although the January survey was determined to be performed sometime between January 18 and 21, 2011. Furthermore, the storage record survey dated November 30, 2011, was incomplete as it was not signed by either the radiation safety officer or the person performing the survey. Finally, the serial number of the survey meter listed on the November 30, 2011, was inaccurate as the survey meter was not in the office prior to November 28, 2011, and so could not have been used to perform the survey in the October 24 to November 24, 2011, timeframe that was suggested by the contract consultant as to when the survey was actually performed.
  8. The leak test certification dated January 25, 2011, signed by the radiation safety officer and the licensee's contract consultant certified that the sealed radioactive sources were leak tested on January 25, 2011, and the test was performed by the contract consultant. This was inaccurate in that travel records showed that the contract consultant was actually on site between January 18 and 21, 2011. Furthermore, the leak test certification dated August 5, 2011, signed by the radiation safety officer and the licensee's contract consultant certified that the sealed radioactive sources were leak tested on March 5, 2012. Either the date of the report or the date of the leak test was inaccurate.
- B. License Condition 15.A of Amendment 1 of License 21-32316-01, applicable from September 18, 2001, until October 23, 2011, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures in the Application received April 11, 2001.

License Condition 15.A. of Amendment 2 of License 21-32316-01, applicable from October 23, 2011, onward requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures in the Application dated April 26, 2011.

Item 9.1, "Equipment List" is an identical representation procedure in both the Application dated April 11, 2001, and the Application dated April 26, 2011. Under it is listed a well counter.

Item 10.12 "Area Survey Procedures" is an identical procedure in both the Application dated April 11, 2001, and the Application dated April 26, 2011. Subitem 10.12.1 states that all areas where radiopharmaceuticals are eluted, prepared, and administered will be

surveyed at the end of each day of use for ambient radiation exposure rates and weekly for removable contamination. Subitem 10.12.2 states that all areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removable contamination. Subitem 10.12.4 states, in part, that surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 disintegrations per minute (dpm). It further states that the results will be recorded as net dpm per 100 square centimeters.

Contrary to the above:

1. No daily contamination surveys could be confirmed to have been performed as required between October 5, 2011, and November 28, 2011. Specifically, the survey meter normally assigned to the licensee (#172810) was sent out for calibration on October 4, 2011, and not returned until November 28, 2011, the survey meter number recorded was not traceable to any survey meter owned by either the licensee or its contract consultant, and the explanation given for the recorded number changed multiple times.
  2. No weekly contamination surveys could be confirmed to have been performed as required between October 5, 2011, and November 28, 2011. Specifically, the survey meter normally assigned to the licensee (#172810) was sent out for calibration on October 4, 2011, and not returned until November 28, 2011, the survey meter number recorded was not traceable to any survey meter owned by either the licensee or its contract consultant, and the explanation given for the recorded number changed multiple times.
  3. From at least August 10, 2010, to April 26, 2012, it could not be confirmed that the licensee had assayed wipes for removable contamination using a procedure sufficiently sensitive to detect 2000 dpm. Specifically, the well counter broke sometime prior to August 10, 2010, and the contract consultant informed the nuclear medicine technologists (NMTs) to assay the wipes using a survey meter with a pancake probe. However, the contract consultant did not provide the NMTs any information to ensure that survey meter with a pancake probe was sufficiently sensitive to detect 2000 dpm. Nor had the contract consultant provided any means to convert the reading from counts per minute to dpm. Furthermore, from October 5, 2011, to November 28, 2011, it could not be confirmed that there was a survey meter in the licensee's office.
- C. 10 CFR 35.61, "Calibration of Survey Instruments" item (a) requires, in part, that a licensee calibrate survey instruments used to show compliance with 10 CFR Part 30 and 10 CFR Part 20 before first use, annually, and following a repair.

License Condition 15.A. of Amendment 2 of License 21-32316-01, applicable from October 23, 2011, onward requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures in the Application dated April 26, 2011.

Item 9.2 "Calibration of Survey Instruments" is a representation in the Application dated April 26, 2011, which states, in part, that all survey instruments will be calibrated and checked in accordance with 10 CFR 35.51[sic]. Subitem 9.2.3 permits the survey meters to be calibrated by any authorized user licensed to perform survey meter calibrations as a service.

Contrary to the above, from August 13 (or 15), 2010, to May 14, 2012, it could not be confirmed that the licensee had calibrated its survey instrument annually. Specially, the November 10, 2011, calibration record was completely identical to August 13 (or 15), 2010, calibration record and the type of radioactive source documented as being used to perform the calibration did not have the strength to calibrate the instrument at the upper range.

- D. License Condition 15.A. of Amendment 2 of License 21-32316-01, applicable from October 23, 2011, onward requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures in the Application dated April 26, 2011.

Item 9.4, "Personnel Monitoring Program" is a procedure in the Application dated April 26, 2011. Subitem 9.4.2 states that all individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a whole body radiation exposure measuring device. Subitem 9.4.3 states that all individuals who handle radioactive material on a regular basis will be issued a finger radiation exposure measuring device.

Contrary to the above, between December 13, 2011, and March 5, 2012, the licensee failed to issue a whole body radiation exposure measuring device to an individual who was occupationally exposed to ionizing photon radiation on a regular basis. Furthermore, the licensee failed to issue a finger radiation exposure measuring device to an individual who handled radioactive material on a regular basis. Specifically, the licensee's nuclear medicine technologist was employed on December 13, 2011, who was occupationally exposed to technetium-99m, a photon emitter, and handled radioactive material on a regular basis was not issued a whole body radiation exposure measuring device and a finger radiation exposure measuring device until March 5, 2012.

- E. License Condition 15.B. of Amendment 2 of License 21-32316-01, applicable from October 23, 2011, onward requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a facsimile dated October 21, 2011.

Pages 5 and 6 of the facsimile contain a procedure titled "Radiation Safety Program. On page 6, under the subheading "Radiation Exposure Records": the procedure requires the licensee to read film badges on monthly basis and for the results to be evaluated by the radiation safety officer.

Contrary to the above, between December 13, 2011, and March 5, 2012, the licensee failed to read film badges on a monthly basis and the results were not evaluated by the radiation safety officer. Specifically, a nuclear medicine technologist began working from

December 13, 2011, but was not assigned a film badge until March 5, 2012, a time period of approximately 75-days. During this 75-day interval, the film badge was not read and the radiation safety officer did not evaluate the results or question why there were no results to be evaluated.

- F. 10 CFR 35.67, "Requirements for Possession of Sealed Sources and Brachytherapy Sources," item (b)(2), requires, in part, that a licensee test, the source for leakage at intervals, not to exceed 6 months or at other intervals approved by the Commission.

Contrary to the above, between June 15, 2010, and March 5, 2012, sealed sources were not leak tested at 6 months intervals, and no other intervals were approved by the Commission. Specifically, leak tests were performed only on the following dates: June 15, 2010, January 25, 2011, and March 5, 2012, (Note: the record was dated August 5, 2011). The time period between the June 15, 2010, test and the January 25, 2011, test was 7 months and 10 days and the time between January 25, 2011, test and the March 5, 2012, test was 13 months and 11 days. Even presuming that there was an August 11, 2011, test for which the licensee did not have records, the intervening intervals would be 6 months, 11 days between January 25, 2011, and August 11, 2011, and 7 months 26 days between August 11, 2011, and March 5, 2012. These intervals all exceeded 6 months.

- G. 10 CFR 35.67, "Requirements for Possession of Sealed Sources and Brachytherapy Sources," item (g) requires, in part, that a licensee in possession of sealed sources conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, between June 15, 2010, and March 5, 2012, the licensee failed to conduct a semi-annual physical inventory of all sealed sources in its possession. Specifically, the licensee's records indicated that physical sealed source inventories were performed on June 15, 2010, July 20, 2011, and March 5, 2012. The time period between each physical sealed source inventory was greater than semi-annually.

- H. Title 10 CFR 35.24, "Authority and Responsibilities for the Radiation Protection Program," item (b) requires a licensee's management to appoint a Radiation Safety Officer (RSO) who agrees, in writing, to be responsible for implementing the radiation protection program. It further states that the licensee, through the RSO ensures that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

License Condition 11 of Amendment 1 of License 21-32316-01, applicable from September 18, 2001, until October 23, 2011, and License Condition 11 of Amendment 2 of License 21-32316-01, applicable from October 23, 2011, onward both name Bradley D. Bastow, D. O., (the licensee) as the RSO.

Contrary to the above, from at least August 10, 2010, to January 31, 2013, the RSO failed to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Specifically, the RSO failed to ensure that: (1) film badges were provided to a nuclear medical technologist ; (2) film badges were read on a monthly basis; (3) sealed sources were leak-tested at intervals



not to exceed 6 months; (4) semi-annual physical inventories were performed; (5) daily and weekly surveys were performed; (6) the survey meter was calibrated; (7) equipment listed in the license was available in the office and functional (survey meter and well counter); (8) a procedure was available to demonstrate that use of a survey meter was sufficiently sensitive to detect 2000 dpm on a series of wipes; (9) the external surfaces of a labeled packages were monitored for radioactive contamination upon receipt; and (10) records were maintained complete and accurate.


The NRC has concluded that the actions described in the Confirmatory Order will provide an adequate response to the violations. Therefore, you are not required to separately respond to this Notice of Violation (Notice).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 3<sup>rd</sup> day of September, 2013

**CONSENT AND HEARING WAIVER FORM**

Bradley D. Bastow, D.O., hereby agrees to comply with the terms and conditions of the Confirmatory Order arising out of an alternative dispute resolution process related to enforcement action No. MA-13-026. Bradley D. Bastow, D.O., understands that the Confirmatory Order will be effective within 20 days of its issuance in the *Federal Register*. By signing below, Bradley D. Bastow, D.O., consents to the issuance of the referenced Confirmatory Order, effective within 20 days of its issuance in the *Federal Register*, and, by doing so, agrees to waive the right to request a hearing on all or any part of the Confirmatory Order.



\_\_\_\_\_  
Dr. Bradley Bastow  
Bradley D. Bastow, D.O.

8/23/13  
Date

As evidenced by your signed "Consent and Hearing Waiver Form" (Enclosure 3) dated August 22, 2013, 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 10 CFR 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 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>. 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

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

Enclosures:

1. Confirmatory Order
2. Notice of Violation
3. Consent and Hearing Waiver

See previous concurrences

FILE NAME: G:\ORAI\IEICS\ENFORCEMENT\Cases\Enforcement Cases 2013\EA-13-025 Bradley Bastow\EA-13-025 Bastow ADR draft final Order.docx

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DATE	07/18/13	07/18/13	07/24/13	07/25/13	
OFFICE	D:FSME	D:OE	D:OGC	RIII	RIII
NAME	Satorious <sup>1</sup> Sun	Zimmerman <sup>2</sup> Marenchin	Scott <sup>3</sup> Hair	Orth	Pederson
DATE	07/29/13	08/08/13	08/07/13	08/29/13	08/29/13

**OFFICIAL RECORD COPY**

- 
- 1 FSME concurrence received via email from R. Sun on July 29, 2013.
  - 2 OE concurrence received via email from T. Marenchin on August 8, 2013.
  - 3 OGC "No Legal Objection" received via email from C. Hair on August 7, 2013.

Letter to Bradley D. Bastow from Cynthia D. Pederson dated September 3, 2013

SUBJECT: CONFIRMATORY ORDER; NRC INSPECTION REPORT  
NO. 03035710/2012-001 AND OFFICE OF INVESTIGATIONS  
REPORT NO. 3-2012-017; BRADLEY D. BASTOW, D. O.

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