



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 27, 2012

Docket No. 03032974

License No. 45-25221-01MD

David Pellicciarini, C.H.P.
Vice President
IBA Molecular North America, Inc.
21000 Atlantic Boulevard, Suite 730
Dulles, VA 20166

**SUBJECT: NRC INSPECTION REPORT NO. 03032974/2011001, IBA MOLECULAR
NORTH AMERICA, INC., MORGANTOWN, WEST VIRGINIA SITE AND
NOTICE OF VIOLATION**

Dear Mr. Pellicciarini:

On December 1, 2011 through January 17, 2012, Todd Jackson of this office conducted a safety inspection at 3601 Morgantown Industrial Park, Morgantown, West Virginia of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in the email from Jason Fowler dated December 21, 2011, was also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation involved the failure to calibrate radiation and contamination measuring instruments. The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

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 review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. As discussed with David Pellicciarini during the exit teleconference on January 17, 2012, your response should also include an evaluation of the potential impact of operating and making package surveys using the uncalibrated well counter during the period December 12, 2008 through December 21, 2011.

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

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Todd Jackson at 610-337-5308 if you have any questions regarding this matter.

Sincerely,

Original signed by Judith A. Joustra

Judith A. Joustra, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Commonwealth of Virginia
State of West Virginia

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

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Enclosure:
Notice of Violation

cc:
Commonwealth of Virginia
State of West Virginia

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NOTICE OF VIOLATION

IBA Molecular North America, Inc.
Dulles, VA

Docket No. 03032974
License No. 45-25221-01MD

During an NRC inspection at 3601 Morgantown Industrial Park, Morgantown, West Virginia conducted on December 1, 2011 through January 17, 2012, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Condition 20 of NRC License 45-25221-01MD requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the licensee's application dated February 13, 2003, (ML030360473). The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations. Item 8.10.2 of the licensee's application dated February 13, 2003, requires that survey instruments be calibrated at one year intervals. The application states that portable survey meters will be calibrated annually, and that the "wipe test" Nal well attached to a gamma spectrometer or a single or multi-channel analyzer" will be calibrated annually.

Contrary to the above, on December 1, 2011, licensee survey instruments were not calibrated at one year intervals and the wipe test Nal well attached to a gamma spectrometer or a single or multi-channel analyzer was not calibrated annually. Specifically, the licensee was using instruments to measure radiation and contamination of packages prepared for shipment that were not calibrated annually. On December 1, 2011, the inspector observed the licensee making direct radiation measurements of packages for shipment to verify that packages were in compliance with transportation regulations in 10 CFR Part 71, using survey meter no. 254176 with calibration that expired on June 24, 2011. Also on December 1, 2011, the licensee was using the wipe test analyzer to verify that packages prepared for shipment satisfied limits for contamination as specified in transportation regulations (10 CFR Part 71). The wipe test analyzer calibration records generated during calibrations beginning December 12, 2008 through December 21, 2011 contained discrepancies and errors sufficient to conclude the calibrations were invalid, and therefore the instrument was not calibrated during the period.

This is a Severity Level IV violation (Enforcement Policy, Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, IBA Molecular North America, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. 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, an order or a

Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 27 day of January 2012