

NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: IBA Molecular North America, Inc. 8614 NW 107 th Terrace Kansas City, Missouri		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region I, 2100 Renaissance Blvd, Suite 100 King of Prussia, Pennsylvania 19406-2713	
REPORT NUMBER(S) 2015-001			
3. DOCKET NUMBER(S) 030-32974	4. LICENSE NUMBER(S) 45-25221-01MD	5. DATE(S) OF INSPECTION March 26, 2015	

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☐ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☒ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

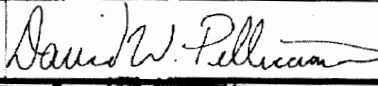
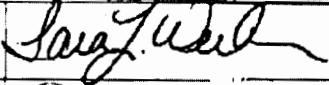
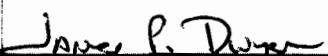

1 Non-cited violation(s) were discussed involving the following requirement(s) and corrective action(s):

Contrary to License Condition No. 19 and item 1.c. of section 8.10.8 of the application dated June 28, 2013, the licensee failed to perform linearity tests on two dose calibrators between October 15, 2014, and March 16, 2015, a period exceeding three months. This violation was identified by the licensee's corporate auditor. The root cause was that the acting site RSO believed the test was required every six months instead of every three months. As corrective action, the licensee immediately performed the required linearity testing. In addition, the acting site RSO set up reminders on his phone so that future linearity tests would be performed timely.

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with the NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11. (Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE	David W. Pellicciarini		4/15/15
NRC INSPECTOR	Geoffrey Warren / Dennis O'Dowd		4/14/15
BRANCH CHIEF			4/17/15

*NRC FORM 591M PART 1 (07-2012) (RI Rev. 09/12/2013)

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SUNSI Review Completed By: / RA / TLWeidner

☒ Public ☒ Non-Sensitive

This document becomes an NRC Official Agency Record once it is signed by the Branch Chief