

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

IBA Molecular North America, Inc.
21000 Atlantic Boulevard
Suite No. 730
Dulles, Virginia 20166

REPORT NUMBER(S) 12-01

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38113

4. LICENSE NUMBER(S)

45-25221-05

5. DATE(S) OF INSPECTION

November 15, 2012

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:

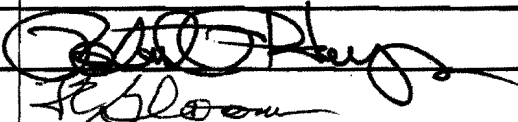

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was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

Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 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 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			
NRC INSPECTOR	Robert P. Hays		11/15/12
BRANCH CHIEF	Tamara E. Bloomer		11/17/12

Docket File Information

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3. DOCKET NUMBER(S) 030-38113	4. LICENSE NUMBER(S) 45-25221-05	5. DATE(S) OF INSPECTION November 15, 2012	
6. INSPECTION PROCEDURES USED 87125	7. INSPECTION FOCUS AREAS 03.01-03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 3210	2. PRIORITY 2	3. LICENSEE CONTACT Michael Roberts, RSO	4. TELEPHONE NUMBER (816) 801-8544
<input type="checkbox"/> Main Office Inspection Next Inspection Date: 11/15/2014			
<input checked="" type="checkbox"/> Field Office Inspection 8614 NW 107th Terrace, Kansas City, Missouri			
<input type="checkbox"/> Temporary Job Site Inspection			

PROGRAM SCOPE

The licensee is authorized for production of activated radionuclides used for PET imaging and medical diagnosis of disease and transferred to a nuclear pharmacy for preparation and distribution to licensees authorized for PET studies. Although the licensee is authorized for production of various radionuclides, only two compounds of fluorine-18 are produced and distributed. Production runs each day except Sunday and start times can vary depending on the amount of F-18 that is required to fill orders for the nuclear pharmacy. The staff working under the license includes a cyclotron engineer and other staff as needed from the nuclear pharmacy.

Performance Observations

During the inspection, the licensee's RSO and staff demonstrated/discussed: (1) survey meter calibrations; (2) ambient and contamination surveys and surveys; (3) hot cell operations and procedures; (4) sealed source inventory; (5) routine security of licensed material; (6) emergency procedures; (7) radiation safety program audits; (8) dosimetry; (9) staff training; (10) effluent monitoring; (11) waste storage and removal; (12) material accountability; (13) contamination events; (14) target events; (15) dosimetry; [CY 2011: 1938mr-DDE; 4900mr-SDE], [2012 to October 7: 5500mr-SDE]

The inspector performed independent radiation measurements which indicated no dose concerns and consistent with licensee survey records and postings.