

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: IBA Molecular North America, Inc. 8614 NW 107th Terrace Kansas City, Missouri REPORT NUMBER(S) 2015001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-38113	4. LICENSE NUMBER(S) 45-25221-05	5. DATE(S) OF INSPECTION March 26, 2015
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6. INSPECTION PROCEDURES USED 87136	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03210	2. PRIORITY 2	3. LICENSEE CONTACT Behailu Desta, RPh, Pharmacy Manager	4. TELEPHONE NUMBER (888) 801-8544
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Main Office Inspection Next Inspection Date: 3/26/2017

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee is a cyclotron that produced fluorine-18 (F-18) for transfer to pharmacy license 45-25221-01MD, under which fluorodeoxyglucose (FDG) and F-18 sodium fluoride (NaF) doses were prepared and distributed to clients. An inspection of the pharmacy license was performed concurrent to this inspection. The licensee employed one cyclotron engineer, one pharmacist, three technologists, one chemist, and two dispatchers, but were in the process of hiring a second pharmacist. The licensee performed three or four cyclotron runs daily as needed based on customer requests. The facility was staffed from around 2:00 am through late morning. Waste F-18 materials were held for decay in storage. The licensee performed annual corporate audits to ensure compliance with regulatory requirements. The maximum exposures received by licensee personnel for calendar year 2013 were 1342 mrem whole body and 4120 mrem extremity, for 2014, 3076 mrem whole body and 7150 mrem extremity, and for January through March of 2015, 304 mrem whole body and 370 mrem extremity.

Performance Observations: The inspectors observed chemistry setup, transfer of materials from the cyclotron to chemistry, QC sampling and analysis, dose preparation and packaging, shipping package preparation and surveys, preparation of shipping papers and labels, transfer of packages to couriers, and handling of returned packages. Licensee personnel demonstrated and described spill procedures, cyclotron maintenance, target preparation and maintenance, stack and effluent monitoring, daily surveys, waste handling and disposal, and other procedures. The inspectors noted no concerns with these activities. Interviews with licensee staff indicated adequate knowledge of radiation safety concepts and procedures. The inspectors performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

For future inspections under this license, the inspector should contact Region I to ask if they would like an inspection of the pharmacy license, 45-25221-01MD, to be performed concurrently.