U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03032974/2008001
Docket No.	03032974
License No.	45-25221-01MD
Licensee:	IBA Molecular North America, Inc.
Address:	100 Executive Drive, Suite 100 Sterling, VA 20166
Locations Inspected:	3601 Morgantown Industrial Park Morgantown, West Virginia
Inspection Dates:	November 17, 2008

Inspector: ___/RA by James P. Dwyer for/_____ _12/17/08_____
Dennis R. Lawyer date
Health Physicist

Approved By: _____/RA/_____ ____12/17/08_____
James P. Dwyer, Chief date
Commercial and R&D Branch
Division of Nuclear Materials Safety

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EXECUTIVE SUMMARY

IBA Molecular North America, Inc.
NRC Inspection Report No. 03032974/2008001

Landauer, the dosimetry vendor, notified IBA Molecular North America, Inc. (IBA or the licensee) on October 14, 2008 that a whole body dosimeter assigned to a pharmacy technician between September 1, 2008 and September 30, 2008 recorded an abnormally high reading. The reading recorded was 8632 millirem deep-dose equivalent, 9630 millirem lens dose equivalent, and 10686 millirem shallow-dose equivalent. The dosimeter had been assigned to a pharmacy technician working at the facility located at 3601 Morgantown Industrial Park in Morgantown, West Virginia. The licensee reported the apparent exposure to the State of West Virginia. The licensee made NRC aware of the apparent exposure in November 2008. Because the licensee is licensed by the State to possess accelerator-produced radioactive material and is licensed by NRC to possess byproduct material, NRC performed a reactive inspection to follow up on the apparent exposure.

The inspector concluded that the abnormally high radiation exposure recorded by the pharmacy technician's whole body dosimeter in September 2008 did not accurately represent the technician's exposure. Furthermore, the inspector concluded that it is likely one or more employees at IBA willfully exposed the pharmacy technician's dosimeter to a source of radiation. The inspector concluded that a more accurate whole body exposure for the month of September would be less than 530 millirem, the cumulative radiation exposure recorded by the technician's extremity dosimetry. The inspector also concluded that the State of West Virginia had regulatory authority over the use of accelerator-produced radioactive material within the State through the end of September 2008.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The inspector reviewed the organization and scope of the licensee's program through a tour of facilities and employee interviews.

b. Observations and Findings

IBA Molecular North America, Inc. (IBA) operates its facility located at 3601 Morgantown Industrial Park in Morgantown, West Virginia. IBA's production hours are Monday through Saturday between midnight and 11:00 AM. IBA has three full time nuclear pharmacists on the staff; however, one of the pharmacists is still in training. IBA employs 4 pharmacy technicians, 26 drivers, and 4 production/quality control personnel.

The main product produced at the facility is fluorine-18 fluorodeoxyglucose (FDG). The fluorine-18 is produced at a cyclotron facility located a short distance away on the University of West Virginia campus. IBA receives the fluorine-18, performs the FDG synthesis and prepares approximately 120 patient dosages each day.

IBA also compounds and distributes 4 to 10 doses of iodine-131 each week; distributes indium-111 once each week; and re-distributes iodine-131 Bexxar and iodine-123 as needed. Only the pharmacists process the iodine-131 and indium-111 materials.

The drivers deliver pharmaceutical products to facilities located within a 150 mile radius of the IBA facility.

c. Conclusions

The majority of products distributed by IBA are accelerator-produced. No violations or safety concerns were identified.

II. Abnormal Dosimetry Result

a. Inspection Scope

The inspector toured the IBA facility, interviewed members of the IBA production staff (including the pharmacy technician who received the report of an abnormally high exposure), reviewed licensee records and reviewed reports provided by the dosimetry processor, Landauer.

b. Observations and Findings

On October 14, 2008, Landauer notified the licensee that a whole body dosimeter assigned to a pharmacy technician between September 1, 2008 and September 30, 2008 received an abnormally high exposure reading. The exposure reading was 8632 millirem deep-dose equivalent, 9630 millirem lens dose equivalent, and 10686 millirem shallow-dose equivalent. The Landauer report stated that the dosimeter indicated a dynamic exposure. The inspector noted that this meant Landauer believed the reported exposure could be accurate because either the dosimeter or the source of radiation was moving when the exposure of the dosimeter occurred. Landauer re-processed the dosimeter and received the same result.

The inspector noted that for calendar year 2008 through August 31, the pharmacy technician had received 2884 millirem deep dose equivalent of whole body exposure, or approximately 360 millirem each month. Because his whole body exposure for the year exceeded IBA ALARA goals, beginning on September 22, 2008, IBA management scheduled the pharmacy technician to work the day shift instead of the night shift. The inspector noted that more radioactive material is handled and higher personnel exposures are expected for employees who work on the night shift.

Pharmacists and pharmacy technicians are issued extremity dosimetry that is to be worn on the fingers of each hand. These dosimeters are exchanged weekly. The results of the extremity dosimeters worn by the pharmacy technician during the month of September 2008 are as follows:

Dates	Left Ring (millirem)	Right Ring (millirem)
9/1-9/7	280	800
9/8-9/14	140	1220
9/15-9/22	80	300
9/22-9/28	30	110
9/29-10/5	MDA	120
Total	530	2550

The inspector noted that the pharmacy technician was right-handed and a review of the tasks performed by the technician demonstrated that the technician's right hand should receive the highest exposure. The inspector noted that the reduction in exposure received by the pharmacy technician after September 22 is due to the rescheduling of his work hours.

The pharmacy technician stated that he always wore his whole body dosimetry and had his extremity dosimetry with him when entering the restricted area of the pharmacy. The pharmacy technician said that he always wore his extremity dosimetry on the fingers of his hands when he handled radioactive material and stored the extremity dosimetry in the left pocket of his lab coat when he was in the restricted area but not handling radioactive material. The inspector noted that the licensee requires employees to survey their dosimetry daily after use to ensure that contamination of the dosimeter does not cause an abnormal reading.

The inspector noted that if the pharmacy technician always had his extremity dosimetry with him when he entered the restricted area of the pharmacy, and the radiation exposure measured by the pharmacy technician's whole body dosimetry is real, the two extremity dosimeters should have also recorded the abnormally high exposure. Because the extremity dosimeters did not record an abnormally high exposure, evidence suggests that the exposure of the whole body dosimeter is not reflective of the exposure actually received by the pharmacy technician. Based on the technician's extremity exposures recorded for the month of September, a more accurate whole body exposure would be less than 530 millirem, the minimum shallow-dose equivalent exposure recorded in the month by the extremity dosimeters.

Radiation dose measurements were performed by the inspector within the facility to identify any abnormally high radiation levels and determine if accidental exposure of the dosimeter was possible. Most areas of the facility measured below 1 millirem per hour. An exception was near the FDG synthesis machine where radiation measurements approached 200 millirem per hour. Radiation levels on the inside of the synthesis machine were much higher. The pharmacy technician and the licensee stated that the pharmacy technician had not worked with the FDG synthesis machine during the month of September.

The inspector noted that the licensee uses an individual storage box system for personnel to store their dosimetry during non-working hours. This storage box is accessible to all employees and is located in a common area. According to the pharmacy technician, during the early part of September, his whole body dosimeter was found separated from his extremity dosimetry on a table near the storage box. The pharmacy technician stated that he found his extremity dosimetry stored properly inside the storage box.

The licensee believes that the whole body dosimeter assigned to the pharmacy technician was exposed to radiation by another pharmacy employee. The pharmacy technician reported he had been the subject of workplace harassment in September and had received a defamatory and anonymous note. The licensee has not identified the employee who sent the note but believes the same individual exposed the pharmacy technician's whole body dosimeter to radiation. IBA management took steps to address the harassment and apparent willful exposure of the dosimeter, including, the reiteration of policies and procedures that describe a zero-tolerance policy for harassment and the consequences if harassment continued. IBA management also installed a security camera to monitor activities in the dosimetry storage area.

c. Conclusions

The inspector concluded that the abnormally high radiation exposure recorded by the pharmacy technician's whole body dosimeter in September 2008 did not accurately represent the technician's exposure. Furthermore, the inspector concluded that it is likely one or more employees at IBA willfully exposed the pharmacy technician's dosimeter to a source of radiation. The inspector concluded that a more accurate whole body exposure for the month of September would be less than 530 millirem, the cumulative radiation exposure recorded by the technician's extremity dosimetry.

III. Worker Exposure Regulatory Authority

a. Inspection Scope

The inspector toured facilities, interviewed staff and reviewed records to identify the sources of radiation exposure received by the pharmacy technician.

b. Observations and Findings

The inspector determined that essentially 100 percent of the radiation exposure received by the pharmacy technician during his employment came from accelerator-produced radioactive material, principally fluorine-18. The inspector noted that the only radioactive material used by IBA that was not accelerator-produced was iodine-131 and small sealed sources of cesium-137 and barium-133. The inspector confirmed that the pharmacy technician did not work with the iodine-131 during calendar year 2008 and, while the technician occasionally performed constancy testing of the dose calibrators using a 254 microcurie cesium-137 source and a 269 microcurie barium-133 source, the inspector noted that the exposure received from these sources would be negligible.

The inspector noted that Section 651(e) of the Energy Policy Act of 2005 authorized the NRC to issue a time-limited waiver (70 FR 51581; August 31, 2005) to allow continued use and possession of naturally-occurring and accelerator-produced radioactive materials (NARM) while the Commission developed a regulatory framework for regulation of the new byproduct material. In the Federal Register on March 18, 2008, the NRC gave notice that on September 30, 2008, the Commission would terminate the time-limited waiver for the State of West Virginia. The inspector noted that the period of the abnormally high radiation exposure recorded on the pharmacy technician's whole body dosimeter was September 1 through September 30, 2008, a time when the State of West Virginia retained jurisdiction for the regulation of accelerator-produced radioactive material within the State. The inspector noted that IBA notified the State of the abnormally high dosimetry report shortly after the report was received in October 2008.

c. Conclusions

The inspector concluded that the State of West Virginia had regulatory authority over the use of accelerator-produced radioactive material within the State through the end of September 2008.

IV. Exit Meeting

On November 17, 2008 an exit meeting was held with the licensee's Radiation Safety Officer and Vice President of Regulatory Affairs, North America. The inspector's conclusions were discussed with the licensee and conveyed verbally to the State of West Virginia.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

S. Duann Vanderslice, Radiation Safety Officer and Vice President of Regulatory Affairs, North America
Ron Lough, Nuclear Pharmacist and Facility Manager
Mark McIntyre, Nuclear Pharmacist
Pharmacy Technician