U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	030-38182/2014-001
Docket No.	030-38182
License No.	47-23035-03
Licensee:	West Virginia University
Address:	P.O. Box 9006 Morgantown, West Virginia 26506
Locations Inspected:	Robert C. Byrd Health Sciences Center One Medical Center Drive Morgantown, West Virginia 26506
Inspection Dates:	May 5-6, 2014
Date Followup Information Received:	April 30, May 19, and June 16, 2014
Exit Meeting:	June 19, 2014

Inspectors:

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Document Name: C:\RawFiles\ML14190B263.doc

EXECUTIVE SUMMARY

West Virginia University
NRC Inspection Report No. 030-38182/2014-001

On Wednesday, March 19, 2014, a dosimetry vendor reported to IBA Molecular North America, Inc. (IBA) that a cyclotron operator working at the West Virginia University (WVU) facility received an extremity exposure of 56,290 millirem (mrem) on the left ring dosimeter, an exposure in excess of the annual occupational dose limit. The cyclotron is operated by IBA for WVU under an agreement for facility use, operations and license applications. IBA is responsible for the production of bulk quantities of flourine-18 (F-18) and nitrogen-13 (N-13) as well as the handling and transportation of all radioactive materials produced under WVU's cyclotron license.

The extremity exposure occurred during the monitoring period of February 17 through February 23, 2014. WVU initiated an investigation to determine the validity of the exposure reading on the ring. WVU notified NRC by telephone on March 19, 2014 and submitted a written report, dated April 14, 2014, in accordance with 10 CFR 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive materials exceeding the constraints or limits." In accordance with Manual Chapter 2800 "Materials Inspection Program," a limited-scope reactive inspection was performed to review the WVU investigation of the high exposure reported for a ring dosimeter used by an employee working at the cyclotron facility. The inspection consisted of review of the licensee's written reports, performance of independent calculations by the NRC staff, interviews with cyclotron workers, and observations at the licensee's facility.

The NRC concluded that the high exposure reported for the ring dosimeter was likely due to contamination of the ring dosimeter. The NRC agreed with the licensee's assessment of the dose to the extremity of the individual to range from 1,995 millirem to 6,860 millirem. Because it is not known if the skin of the hand was actually contaminated, WVU staff assigned a dose of 6,860 millirem to the individual for the period of February 17 through 23, 2014, which included the dose from skin contamination and the maximum weekly dose based on dosimetry records. The inspectors reviewed the licensee's assessment of the dose to the individual and found it to be reasonable.

The NRC identified one violation of 10 CFR 20.1501: failure to perform an adequate survey. Specifically, the individual working under the WVU license did not properly monitor his hands before leaving the restricted area.

REPORT DETAILS

1. Scope of the Inspection

a. Inspection Scope

The inspectors performed a limited scope, reactive inspection to review the WVU investigation of a high exposure reported for a ring dosimeter used by an employee working at the cyclotron facility. The inspection consisted of review of the licensee's written reports, performance of independent calculations by the NRC staff, interviews with cyclotron workers, and observations at the licensee's facility.

b. Observations and Findings

On March 19, 2014, the licensee's dosimetry vendor reported that a left hand ring dosimeter, used for monitoring extremity dose, recorded an exposure of 56,290 millirem for the monitoring period February 17, 2014 through February 23, 2014. The WVU Radiation Safety Officer (RSO) contacted the NRC Region I office by telephone on March 19 to inform the NRC that they would be making a 30-day report of this exposure in accordance with 10 CFR 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive materials exceeding the constraints or limits." A report was issued dated April 14, 2014.

Inspectors reviewed the licensee's report and requested additional information which was received on April 30, 2014, by electronic mail. Inspectors met with licensee representatives on May 5 and 6, 2014 to interview employees, observe demonstration of activities performed by the employee, and review the facility. The licensee submitted a revised dose assessment for the employee in a letter dated May 19, 2014, which was reviewed by NRC staff.

c. Conclusions

The inspectors performed a limited scope, reactive inspection of the report of a high exposure measured on an extremity dosimeter. One violation of NRC requirements was identified and is discussed in Section 3, "Activities Related to the High Dosimeter Exposure," of this report. The inspectors reviewed the licensee's assessment of dose to the individual, as described in Section 4, "Dose Assessment," and found it to be reasonable.

2. Organization and Scope of the Program

a. Inspection Scope

The inspectors determined the organization and scope of the activities performed under License No. 47-23035-03 during the monitoring period of the reported high extremity exposure through interviews with licensee staff and review of selected records.

b. Observations and Findings

License No. 47-23035-03 authorizes the manufacture and production of radiochemicals resulting from activation of materials using a cyclotron. This license was issued to WVU, which owns the cyclotron. The cyclotron was operated by IBA Molecular North America, Inc. (IBA) employees, under an agreement with WVU. Under this agreement, the IBA employees followed the requirements of the WVU cyclotron license; dosimetry was provided to IBA employees at the cyclotron through the IBA dosimetry vendor; and audits of the cyclotron program were performed by IBA staff.

The cyclotron was used primarily to produce fluorine-18 (F-18) for use in positron emission tomography (PET) imaging studies. The bulk dose containers of F-18 were transferred to the IBA radiopharmacy at 3601 Morgantown Industrial Park, Morgantown West Virginia where patient doses were drawn and commercially distributed under License No. 45-25221-01MD, issued to IBA. The required quality control (QC) testing of the F-18 materials was performed under the IBA pharmacy license at their Morgantown, West Virginia location.

Over the past few years, the cyclotron was also used to produce N-13 for research and for PET studies at the WVU hospitals. In 2014, N-13 was produced usually on Tuesdays and Thursdays. Because of the 10-minute half-life of N-13, this material was transferred directly from the cyclotron license to the WVU hospitals; therefore, the QC testing of this material was performed under the cyclotron license by the IBA employees.

Three IBA employees performed all cyclotron operations. One individual was the cyclotron engineer. The other two individuals were cyclotron operators working under his supervision. For radiation safety purposes, the IBA employees report to the WVU cyclotron RSO, who also is the RSO for the WVU medical broad scope license and university research broad scope license.

c. Conclusions

The organization and scope of activities were as described in the licensee's application and license.

3. Activities Related to the High Dosimeter Exposure

a. Inspection Scope

The inspectors interviewed cyclotron employees and WVU radiation safety staff members to determine the activities performed during the week of February 17 through 23 that may have contributed to the high dosimeter exposure. The inspectors reviewed the written information provided by the licensee which concluded that the exposure most likely was the result of contamination of the ring dosimeter. The inspectors performed independent calculations to determine if the high dosimeter exposure was likely due to contamination or due to radiation fields.

b. Observations and Findings

During the week of February 17 through 23, the cyclotron produced F-18 daily, and N-13 on Tuesday and Thursday, in accordance with the normal production schedule. The cyclotron engineer and cyclotron operator A performed work all that week because cyclotron operator B worked at the IBA pharmacy location in Morgantown, West Virginia that week. Cyclotron operator A performed cyclotron operation activities, cyclotron maintenance activities, N-13 dose drawing and N-13 QC testing that week. Cyclotron operator A had been employed by IBA 13 years performing cyclotron operation and maintenance. In February 2013, cyclotron operator A began performing N-13 QC testing. In February 2014, cyclotron operator A began drawing the N-13 dose used in QC testing.

(1) Potential exposure to radiation fields

Based on the cyclotron operation and maintenance activities performed during that week, it is unlikely that the dose of 56,290 millirem on the left ring dosimeter was due to work in radiation areas during cyclotron maintenance. The duration of time was not sufficient for the left ring dosimeter to receive such a high dose from radiation exposure. In addition, the doses to the right ring dosimeter (6,540 millirem) and whole body dosimeter (166 millirem) would likely have been higher if the dose were from radiation exposure during cyclotron maintenance activities. Cyclotron operator A also wore a RADOS electronic dose monitor, which did not detect any unusual dose readings and did not alarm.

Cyclotron operator A performed the dose drawing of the N-13 QC sample dose for the first time during the week of February 17 through 23. This process occurred in the cyclotron room in a laminar flow hood behind an L-block shield. Cyclotron operator A placed the N-13 bulk dose vial into a holder on a Biodex dose drawing device and moved it into position for dose drawing. At this facility, a 0.5 milliliter (ml) insulin syringe was used to obtain 0.4 ml of N-13. Because the 0.5 ml insulin syringe was too small to place into the shielded syringe holder on the Biodex device, cyclotron operator A held the unshielded syringe during the dose drawing, and re-capped the syringe prior to placing it into a shielded transport container. This procedure took about 5 minutes. The exposure to the extremity dosimeter occurred during the first week that Cyclotron operator A performed this operation.

The syringe, in its shielded transport carrier, was then moved through the pass-through area from the cyclotron room to the sterile room for testing. Testing was done in a laminar flow hood where the QC sample was prepared for analysis behind an L-block shield. Cyclotron operator A prepared the QC sample by injecting the sample from the syringe into a shielded test tube, adding saline solution and a carrier solution, then drew a sample of this mixture for injection into the high-pressure liquid chromatography (HPLC) analyzer. The syringe was handled without a syringe shield because, according to the cyclotron engineer, the syringe is too small for the available syringe shields. According to cyclotron operator A, this procedure takes about 10 minutes to perform. Cyclotron operator A had performed this procedure for about a year prior to the week that the extremity dose recorded a high exposure.

According to IBA and WVU staff, the 68.7 millicuries of N-13 on Tuesday had a specific activity of 15 millicuries per ml, and the N-13 produced on Thursday had a specific activity of 18 millicuries per ml. NRC staff calculated the gamma dose rate from 0.4 ml of N-13 in the syringe to be about 35-40 R/h. Therefore, it is unlikely that radiation exposure during 15 minutes of handling the QC dose in the syringe would result in a dose of 56,290 millirem to the left ring dosimeter.

(2) Potential exposure from contamination

The QC testing was the last activity performed by cyclotron operator A on Tuesday and Thursday. After completing the testing, cyclotron operator A left the restricted area. Cyclotron operator A did not remember if he performed surveys of his hands or feet prior to leaving on either day, and no alarms were reported on survey instruments or area monitors in the restricted area. Cyclotron operator A stored the whole body dosimeter, and both ring dosimeters, in the assigned storage drawer where all dosimetry was kept when not in use.

Because unusual doses were reported on unused dosimeters for the week of February 17 through 23, 2014, IBA and WVU staff suspected that cyclotron operator A had contaminated the left ring dosimeter. The following doses were reported:

Dosimeter	Exposure
Cyclotron operator A – whole body	166 millirem
Cyclotron operator A – left ring	56,290 millirem
Cyclotron operator A – right ring	6,540 millirem
Control – whole body	850 millirem
Control – ring	1,053 millirem

Inspectors observed that the dosimeter storage was a plastic box containing 15 drawers (3 columns by 5 rows, with total box dimensions approximately 7 inches high by 9 inches wide). Assigned dosimeters were stored in the labeled drawers as shown in Figure 1 below. The drawer containing cyclotron operator A's dosimeters was in the center of the storage box, with control dosimeters in drawers directly above and directly below that drawer. NRC and licensee calculations agreed that doses reported on the Control Dosimeters could be explained by the close proximity to cyclotron operator A's dosimeter in its drawer if the contaminated dosimeter was put into storage shortly after becoming contaminated. In addition, NRC staff calculations also indicate that the dose reported on cyclotron operator A's right ring dosimeter, stored linked to the left ring dosimeter, could be explained by proximity to the contaminated ring dosimeter.

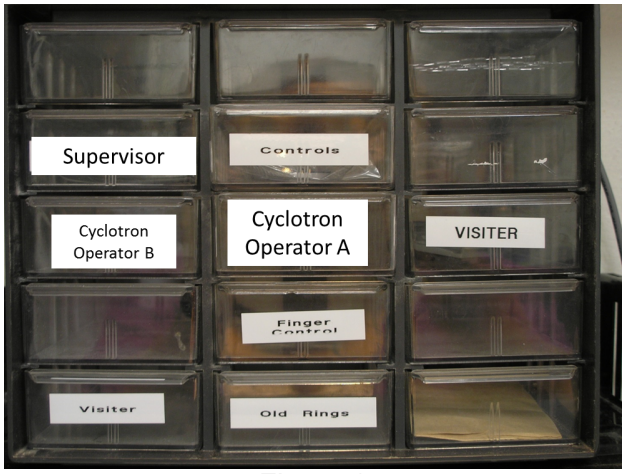

Figure 1

WVU staff and NRC staff independently used the VARSKIN code, and each determined that a dose of 56,290 millirem to the ring dosimeter could occur if 33 microcuries of N-13 were on the surface of the dosimeter, and both beta and gamma radiation penetrated the dosimeter. NRC staff calculated 33 microcuries to be in a volume of 2.2 microliters (2.2 cubic millimeters) of the N-13 material with a specific activity of 15 millicuries per ml. This very small volume could cause contamination that would not readily be visible.

WVU staff stated that such contamination of the ring could occur if the needle of the syringe penetrated the glove near the ring while re-capping. According to the WVU report, during an interview, cyclotron operator A stated that the needle might have pierced the gloves. However, during the NRC interview, cyclotron operator A stated that he did not recall piercing his skin or his gloves with the needle on either day that week. During the inspection, WVU staff agreed that it was unlikely that a needle had pierced cyclotron operator A's skin, because such an event is painful enough that the individual would definitely recall it. The supervisor was present in the same room during the QC dose drawing and does not recall anything unusual happening during Tuesday or Thursday activities.

NRC staff believe the gamma dose rate from 33 microcuries of N-13 on the ring dosimeter (190 milliroentgen per hour [mR/h] at 1 centimeter (cm) away, and 0.019 mR/h at a meter away) would easily be detected during a hand survey prior to exiting but would not be detected by area monitors at ceiling height in the room set to alarm at 100 mrem/h. Because of the ten minute half-life of N-13, contamination of the dosimeters was not detected the next working day, nor was contamination identified by the dosimetry vendor.

The regulation set forth in 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. The inspectors determined that one violation

of 10 CFR 20.1501 occurred for the failure to perform an adequate survey. Specifically, cyclotron operator A did not perform an adequate survey of his hands prior to leaving the restricted area.

c. Conclusions

The inspectors identified a violation for the failure to perform an adequate survey pursuant to 10 CFR 20.1501. Specifically, cyclotron operator A did not perform an adequate survey of his hands prior to leaving the restricted area. NRC staff determined that contamination with 33 microcuries of N-13 on a ring dosimeter would result in a dose rate of 190 mrem/h at 1 cm away, and believe such contamination would have been detected if hands were monitored as required prior to exiting the restricted area.

The inspectors concluded that the reported radiation exposure of 56,290 millirem on the left ring dosimeter could not be the result of only exposure to radiation levels from activities performed by cyclotron operator A during the week of February 17 through 23, 2014. NRC staff agreed with the licensee's conclusion that the ring dosimeter likely was contaminated and caused most of the reported exposure.

4. Dose Assessment

a. Inspection Scope

The inspectors reviewed the licensee's assessment of the actual dose that was assigned to the individual. The NRC also performed independent calculations to determine if the licensee's assumptions and conclusions were reasonable.

b. Observations and Findings

WVU staff, with the assistance of staff from IBA, performed a dose assessment to determine the reasonable dose that will be assigned to cyclotron operator A based on their conclusion that the reported exposure was the result of contamination on the ring dosimeter. The licensee assessed dose using three scenarios: 1) assessment of dose to the individual based on historical records of dose to cyclotron operator A and the cyclotron engineer performing similar activities; 2) assessment of dose to cyclotron operator A's left hand from exposure due to the contamination ONLY on the left ring dosimeter; and 3) assessment of dose to cyclotron operator A's left hand assuming the skin was contaminated with the same amount of material as on the left ring dosimeter.

Based on dosimetry records for 2014, the licensee estimated that cyclotron operator A's weekly dose to the extremity dosimeters ranged from 40 to 400 millirem, and the weekly extremity dosimeters for the cyclotron engineer, performing similar activities, ranged from 40 to 1,210 millirem (mrem). The licensee elected to use 1,210 mrem as an appropriate estimate of dose to cyclotron operator A, based on exposure records from 2014.

Using the 33 microcurie estimated activity of the contamination on the left ring dosimeter, WVU staff used the VARSKIN 4 code to calculate a dose of 785 millirem to

cyclotron

operator A's left hand if the dose resulted from contamination on the ring only. The licensee assumed point source geometry, an irradiation time of 15 minutes, an irradiation area of 10 square centimeters (cm^2), a 7 milligram per cm^2 skin density thickness and no air gap. NRC staff calculations using the VARSKIN 4 code were in agreement.

Although the WVU staff stated that there was no direct evidence of skin contamination, they used the VARSKIN 4 code to calculate a dose of 5,650 mrem to cyclotron operator A's left hand, assuming that 33 microcuries on N-13 was located on the skin. They assumed an irradiation time of 1000 minutes and an irradiation area of 10 cm^2. NRC staff calculations using the VARSKIN 4 code were in agreement.

WVU determined a range of actual dose to cyclotron operator A's left hand to be 1,995 mrem (lower bound) to 6,860 mrem (upper bound). The lower bound is based on a dose of 785 mrem due to exposure from contamination on the ring plus 1,210 mrem based on the maximum weekly dose reported for the cyclotron engineer performing similar activities. The upper bound is based on a dose of 5,650 millirem due to skin contamination, plus 1,210 millirem as before. The licensee determined that the range of dose to the right extremity was between 180 mrem and 1,040 mrem. According to the revised report dated May 19, 2014, WVU assigned cyclotron operator A a dose of 6,860 mrem to the left extremity and 1,040 mrem to the right extremity for the week of February 17 through February 23, 2014.

c. Conclusions

NRC staff agrees that contamination of the ring dosimeter occurred. Because of the short half-life of N-13 and the failure to survey cyclotron operator A's hands prior to leaving the laboratory on one or more days during the week of February 17-23, 2014, it cannot be known if the skin of the hand was actually contaminated or the extent of any skin contamination. Therefore, the NRC staff believes that dose assigned by the WVU staff to the left hand of cyclotron operator A for the period of February 17-23, 2014, as stated in the report dated May 19, 2014 to include the total dose from the dose history and dose from contamination on the skin, was reasonable.

5. Facilities and Equipment

a. Inspection Scope

The inspectors reviewed the facilities and equipment used by the cyclotron operators during the monitoring period of February 17 through 23, 2014. Because renovation of the facility occurred since that time, the inspectors reviewed diagrams of the facility as it was in February, interviewed employees, and observed similar equipment in alternate locations.

b. Observations and Findings

The cyclotron facility is located in the basement of the Robert C. Byrd Health Sciences Center. Access to the cyclotron area is restricted to IBA employees and WVU radiation

safety staff employees. Within the cyclotron facility, additional access controls were used for entry into restricted areas where bulk quantities of radionuclides were handled. A Ludlum 177 hand-and-foot monitor was located near the exit of the restricted areas where employees were expected to survey their hands and feet before leaving the restricted areas. In addition, the restricted area contained an area monitor which was set to alarm at 100 mrem/hour. The licensee also maintained several portable survey meters within and outside of the restricted areas.

c. Conclusions

The inspectors determined that the facilities and equipment were as described in the license, and were adequate to conduct operations in a safe manner. No violations were identified.

6. Training

a. Inspection Scope

The inspectors reviewed the training of cyclotron operator A through observation of simulated activities by cyclotron operator A, interviews with licensee employees and review of selected records.

b. Observations and Findings

Cyclotron operator A has been employed at the WVU cyclotron for 13 years. For most of that time, cyclotron operator A worked only on cyclotron operation and maintenance, and received classroom-type training through IBA and on-the-job training by the cyclotron engineer. Annual refresher training was also attended by cyclotron operator A.

Training given by IBA included the administrative and radiation safety aspects for job performance. Cyclotron operator A described a variety of practices that were stressed in training, such as: employees are expected to wear proper protective clothing (lab coat, safety glasses, and gloves); employees are also expected to monitor hands and feet before leaving the restricted area; employees are expected to wear all assigned dosimetry and return dosimeters to assigned storage areas when not in use.

In February 2013, cyclotron operator A began assisting the cyclotron engineer by performing the QC testing of the N-13 labelled ammonia. For this activity, the cyclotron engineer provided cyclotron operator A with a QC sample in a syringe. The sample was mixed with other chemicals and the resulting mix analyzed in the HPLC analyzer. Cyclotron operator A learned the procedure through on-the-job training from the cyclotron engineer. Both cyclotron operator A and the cyclotron engineer described the focus on radiation safety and the correct chemical technique. Cyclotron operator A performed this procedure for about a year, and no significant differences were noted in his weekly dosimeter reports. The cyclotron engineer stated that cyclotron operator A was a good worker who paid attention to detail.

In July 2013, the WVU radiation safety staff initiated an ALARA review of the dose of 3,940 mrem in one week to the cyclotron engineer left ring dosimeter. The review determined that the dose was due to the cyclotron engineer performing all of the chemistry of the N-13 bulk doses and the increase in the N-13 production. One of the corrective actions was to train additional employees to work with the bulk N-13. In February 2014, cyclotron operator A was taught to draw the QC sample dose through on-the-job training provided by the cyclotron engineer. In addition, the cyclotron engineer stated that he was present in the area when cyclotron operator A was performing the QC sample dose drawing. The first week that cyclotron operator A performed the QC sample drawing was February 17-23, 2014, the same week in which the high exposure was identified on the left ring dosimeter.

Cyclotron operator A and the cyclotron engineer provided similar descriptions of the QC sample dose drawing procedure. Both stated a syringe shield was NOT used when drawing of the QC sample because they did not have a small enough syringe shield. Neither individual had training in safe handling of syringes or safe methods for re-capping syringes. Inspectors noted that the packaging in which the syringe was received stated “do not re-shield used needle.” It is standard practice in the medical industry to discard a needle after use without capping it, by placing it into a “sharps” container for disposal. However, because the sample was drawn into the syringe and needed to be taken to another area for testing, the needle was re-capped by hand at the WVU cyclotron. The cyclotron engineer noted that, if the needle were slightly bent, it could even pierce the cap when re-capping. The lack of a syringe shield and the practice of re-capping the syringe needle contributed to radiation exposure of the hands. Re-capping the needle by hand had the potential for piercing the gloves and/or hands with the needle, especially considering the small size of the needle and its cap.

During the inspection, cyclotron operator A performed a simulated drawing of a QC dose in an area where no radioactive materials were used or stored. During the simulated procedure, cyclotron operator A wore lab coat, safety glasses, two pairs of gloves and all assigned dosimeters, which he stated he normally wore when working with N-13. Cyclotron operator A performed the simulated dose drawing smoothly and efficiently, using the same type of equipment that was used in February 2014.

The radiation safety training provided to cyclotron operator A was as described in the license. The inspectors noted that if the left ring dosimeter was contaminated by piercing of the protective gloves by the needle of the syringe, a contributing factor may be insufficient training in handling of syringes and re-capping of the syringe, a topic outside the scope of NRC regulations.

c. Conclusions

No violations were identified in the area of training.

7. Exit Meeting

The inspectors summarized the preliminary results of the site inspection prior to leaving the site on May 6, 2014. Following the site inspection, WVU submitted an amended investigation report. On June 19, 2014, the inspectors presented the final results of the inspection by telephone.

ATTACHMENT: SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

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Cyclotron Engineer #*
Cyclotron Operator A #
Cyclotron Operator B
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Craig R. Petzhold, Site Manager (Morgantown Facility) #*
Jason Fowler, Site RSO (Morgantown Facility) #

NRC Staff
Farrah Gaskins, Health Physicist #*
Betsy Ullrich, Senior Health Physicist #*
Blake Welling, Chief, Commercial Industrial, R&D, and Academic Branch #*

#Present at entrance meeting
*present at exit meeting

INSPECTION PROCEDURES USED

Manual Chapter 2800, “Materials Inspection Program”

Inspection Procedure 87103, “Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing”

Inspection Procedure 83501, “Significant Uncontrolled Radiation Exposure”

LIST OF DOCUMENTS REVIEWED

Licensee Incident Report dated April 14, 2014
Response to questions dated April 30, 2014, with attachments (electronic mail)
Licensee’s Amended Report dated May 19, 2014
Records of Occupation Exposure 2013 through 2014
Schematic drawings of Facility prior to May 2014
Employee RADOS Logs 2013-2014
Ludlum 177 calibration records 2013
July 2013 ALARA Program Investigation Report

LIST OF ACRONYMS USED

cm	centimeter
IBA	IBA Molecular North America, Inc.
F-18	fluorine-18
HPLC	high-pressure liquid chromatography analyzer
ml	milliliter
mrem	millirem
N-13	nitrogen-13
PET	positron emission tomography
QC	quality control
RSO	Radiation Safety Officer
R/h	roentgen per hour
WVU	West Virginia University