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February 24, 2012

U.S. Nuclear Regulatory Commission ATTN.: Document Control Desk Washington, DC 20555

03032974 201001

RE: Reply to a Notice of Violation IBA Molecular North America, Inc., Dulles, VA [For the site in Morgantown, WV] License No. 45-25221-01MD

To Whom It May Concern,

This is in reply to the Notice of Violation (NOV) dated January 27, 2012, received by IBA Molecular North America, Inc. (IBA), on February 6, 2012. In the NOV, one violation was identified. In addition to replying to the violation, IBA was asked to "include an evaluation of the potential impact of operating and making package surveys using the uncalibrated well counter during the period December 12, 2008 through December 21, 2011."

The Cited Violation

From the NRC's January 27, 2012 letter: "Contrary to the above, on December 1, 2011, licensee survey instruments were not calibrated at one year intervals and the wipe test NaI well attached to a gamma spectrometer or a single or multi channel analyzer was not calibrated annually."

IBA's Reply

Two instruments were identified as being out of calibration. One was a survey meter that was being used for package surveys and the second was the Nal well counter / single channel analyzer that was used to analyze wipe tests for removable contamination from packages. The corrective actions for each are addressed separately below.

With regards to the survey meter being out of calibration, this violation occurred due to an oversight on the part of the staff at the facility. They had mistakenly thought the instrument was due for calibration later in December 2011, and they also misread the calibration sticker on the side of the survey meter.

To correct this, the survey meter in question was removed from service and an in-calibration survey meter was placed into service.

To avoid further violations, the Site RSO will improve the record keeping regarding the survey meter calibration due dates. Additionally, he will also add a daily check of the calibration data by the courier supervisor for the instrument in use for packaging surveys (which was the out of calibration instrument in this instance).

NMSS/RGNI MATERIALC-004

Full compliance was achieved as of the date of the inspection, December 1, 2011, when the out of calibration survey meter was removed from service.

With regards to the Nal well counter being out of calibration, there are a couple of reasons for this occurring. First, in the detector efficiency calculations, an incorrect half life value was used for decay-correcting the activity of the Ge-68 reference standard. The calibration certificate sent with the reference standard incorrectly lists Ge-68's half-life as 207.8 days rather than 270.8 days (a copy of the calibration certificate is attached). This error was not caught by site personnel and it was propagated in subsequent calculations, which impacted the detector efficiency calculations. Second, one of the records (Sep 30, 2010) had an apparent counting error, as the efficiency determined on that record differed from efficiencies taken before and after that date. Third, the data discrepancies were not identified, investigated, and corrected by the responsible site staff.

To correct this, the most recent efficiency and MDA calculations have been corrected (using the proper half-life value for Ge-68) and a new set of action levels developed.

To avoid further violations, the following steps will be taken:

- 1) The correct half life value will be used in the efficiency calculations to ensure the reference standard activity is properly decay-corrected.
- 2) The Site RSO will exercise greater diligence with reviewing the records and trending the data.
- 3) In the future, the efficiency and MDA records will be second-checked by corporate radiation safety staff.
- 4) The person on site designated with the responsibility for performing this task will receive additional training.

Full compliance was achieved on February 24, 2012, with the correction of the calculations and revision of the action level posting.

As noted above, in addition to identifying the corrective actions for the violation, the NRC asked IBA to evaluate the potential impact of using the uncalibrated well counter from December 12, 2008 through December 21, 2011.

From October 3, 2008 through September 23, 2009, the well counter efficiency determinations were made using a Cs-137 reference standard. The highest observed efficiency value for Cs-137 during this period was approximately 22%. In the range of energies of interest, higher energy emissions tend to lead to a lower detector efficiency. The use of Cs-137 for an efficiency determination tends to underestimate the actual efficiency for F-18 (the primary radionuclide of interest at IBA's facility), due to Cs-137's higher energy emissions (662 keV versus 511 keV) and F-18s two photons per positron decay (two 511 keV annihilation photons).

The action level in cpm is determined in the following manner:

Action level (cpm) = Action level (dpm) x Efficiency
$$\left(\frac{c}{d}\right)$$

Understating the efficiency will lead to a more conservative action level in cpm being assigned. Thus, no adverse impact to making package surveys is anticipated during this period of time that the Cs-137 reference standard was used to determine the detector efficiency. On September 24, 2009 a Ge-68 reference standard was used to attempt to more accurately model F-18's emissions and the well counter's efficiency. As noted above, the erroneous (too low) half life from the source manufacturer's calibration certificate was used to decay-correct the source activity.

The efficiency is determined in the following manner:

 $Efficiency = \frac{Reference standard net count rate (cpm)}{Reference standard decay corrected activity (dpm)}$

Since the half life used in the source activity decay correction was too low (207.8 days versus 270.8 days), the decay-corrected activity was too low. Having a decay-corrected activity that is too low causes the efficiency to be overestimated. When the action level in cpm is determined in the same manner as discussed above, the overestimated efficiency leads to an action level in cpm that is too high. Since action levels from September 24, 2009 and on were overstated (in cpm terms), this introduces the potential for an outgoing package shipment to have been released with contamination levels above the allowable limits.

IBA believes there is an important factor that mitigates the potential for an outgoing package having been released with removable contamination levels in excess of the limits. Although the action level posting specified a higher action level, IBA staff at the Morgantown facility have been told to use an action level of 100 counts in 0.1 minute, which is lower than the calculated action level. The reasons for use of this lower value are that it is a number that is easy to remember and it is fairly conservative. The use of this conservative, easier-to-remember value as an action level acted to reduce the potential for packages to be released from IBA's facility with excessive levels of removable contamination.

Thank you for your consideration of the above. If any additional information is needed, please do not hesitate to contact me at (424) 206-2480.

Sincerely,

David W. Pellicciarini, CHP Vice President, RA/QA/EHS IBA Molecular North America, Inc.

cc: Regional Administrator US Nuclear Regulatory Commission, Region I 475 Allendale Road King of Prussia, PA 19406-1415

CERTIFICATE OF CALIBRATION

MODEL BM08 POSITRON REFERENCE STANDARD

Radionuclide: Germa	nium 68/ Gallium 68	Activity:	550.2	nCi	
			20.36	kBq	
Serial Number: BM0	806808273109				
Reference Date:	October 22, 2008	Half Life: 207.8 days			

Source Description:

This rod source is approximately 12 millimeters in diameter and 75 millimeters in length. The radionuclide is deposited into the round end of the rod source and sealed with epoxy.

Method of Calibration:

The standard was prepared using an aliquot measured gravimetrically from a solution calibrated against a Direct Traceable National Institute of Standards and Technology (NIST) stundard. RadQual's contract manufacturer. International isotopes of Idaho Inc. actively participates in the Radioactivity Measurement Assurance Program conducted by NIST.

Total Uncertainty (95% Confidence Level) 3.76%

J-B. Dal 10.22.08 Calibration Technologist

Date

Radiation Protection:

The Rod calib ation source should be handled, stored and disposed as required by your institutions rules and guidelines.

This source was wipe tested per approved procedures and found to be free of leakage.

J-B. Dan

Wipe Test performed by

10.22.08 Date

Contamination/leakage tests should be conducted on a regular basis. The method used to determine contamination or leakage should be sensitive enough to accurately detect levels of less than 5 nanocuries.

RadQual, LLC ~ 114 Barrington Town Square #124 - Aurora, Ohio 44202 - (603-513-1221 - (603) 415-0160 Fax

F-96 rev A Gn 68 rod certificate of calibration BM0806808273109