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November 2, 2009

Betsy Ullrich  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

For IBA Molecular Site In:  
Kansas City, Missouri

**RE: Reply to Request for Additional Information Concerning IBA Molecular's Application for New NRC RAM License for Accelerator at IBA KC MO - 45-25221-05 - Control Number 144065**

Dear Ms Ullrich:

03038113

Please find below IBA Molecular North America, Inc.'s responses to your questions regarding the license application for the Kansas City, MO, site. The sections below are taken from the NRC's letter:

1. In Item 5 of your application, you requested "any byproduct material with atomic numbers 3 through 83" in the form of sealed sources, not to exceed 5 millicuries per source and 50 millicuries total. However, you did not provide manufacturer and model numbers. We cannot authorize sealed sources without verifying that the manufacturer has registered the model you intend to possess. Please provide the manufacturer and model numbers for the sealed sources you intend to possess. Alternately, we could authorize you to possess any sealed sources as authorized in 10 CFR 35.65.

In light of the foregoing, IBA Molecular requests authorization to possess any sealed sources as authorized under 10 CFR 35.65.

2. In Items 8.7.1 and 8.7.2, you request that, for a period not to exceed 60 days in any calendar year, the licensee may permit a visiting person (Radiation Safety Officer, cyclotron operator or authorized user) to function in those positions without amending the license. A similar activity is authorized for medical activities in the regulations of 10 CFR 35.24, but not in other Parts of the regulations. In addition, 10 CFR 35.24 has additional constraints on the appointment, and requires notification of the NRC. The NRC recognizes that the RSO may be away for short periods of time, and does not require that the RSO be present at all times of use of materials. In addition, the persons named as authorized users on your license are authorized to use, or supervise the use of, materials at your facility. Therefore, visiting persons working at your facility may work with licensed materials under the supervision of one of the authorized users.

Thank you for the clarification. IBA Molecular will utilize the provisions outlined in the last two sentences of the above paragraph.

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3. Item 9 of your application states that exposure rates in Unrestricted Areas will be less than 0.6 millirem per hour (100 millirem per week). The NRC requires that exposure rates in unrestricted areas not exceed 2 millirem in any one hour, and not exceed 100 millirem in any one year. Explain how exposure rates of 0.6 millirem in an hour will not exceed the NRC limit of 100 millirem in any one year. Also, confirm that you will correct the "IBA Molecular Thresholds of Action" table entitled "Meter Readings Exposure Limits..." in which Criteria #2 for Unrestricted Areas states a threshold of "100 millirem in any 7 consecutive days".

This paragraph of the application was in error, and unfortunately was not corrected prior to submission to the NRC. IBA Molecular will abide by the requirements of 10 CFR 20.1301, requiring that the dose to an individual member of the public not exceed 100 mrem in a year, and that the dose in any unrestricted area from external sources will not exceed 2 mrem in any one hour.

IBA Molecular has sent out an update to its facilities to change Criteria #2 from "100 mrem in any 7 consecutive days" to "100 mrem in a year".

4. Item 8.10.2 states that IBA will calibrate dose calibrators, well counters, gamma spectrometers, air effluent monitors and other site area monitors. Confirm that these instruments will be calibrated in accordance with manufacturer recommended procedures and frequencies, or other industry standards.

IBA Molecular confirms that these instruments will be calibrated in accordance with manufacturer recommended procedures and frequencies, or other industry standards.

5. Confirm that all instruments used for measurements related to air and effluent monitoring (such as rotometers and other flow rate or volume measurement instruments) will be calibrated in accordance with manufacturer recommended procedures and frequencies or other industry standards.

IBA Molecular confirms that these instruments will be calibrated in accordance with manufacturer recommended procedures and frequencies, or other industry standards.

6. Item 8.11 of your application states that, under certain circumstances, liquid wastes may be disposed into the sanitary sewer if the wastes are readily soluble or dispersible in water. However, the current regulation in 10 CFR 20.2003 requires that such wastes must be "...readily soluble (or readily dispersible biological material) in water...". Confirm that you will correct this procedure to allow disposal into the sanitary sewer only of wastes that are readily soluble in water, or wastes that are readily dispersible biological materials.

IBA Molecular confirms that we will correct this procedure to allow disposal into the sanitary sewer system only of wastes that are readily soluble in water or wastes that are readily dispersible biological materials.

7. Although your Cost Estimate for decommissioning of the accelerator facility is in a different format than the model Decommissioning Funding Plan and Cost Estimate recommended in NRC guidance (NUREG-1757, "Consolidated NMSS Decommissioning Guidance," Volume 3, "Financial Assurance, Recordkeeping and Timeliness," Part II and Appendix A [NUREG-1757, Vol.3]), the appropriate areas were addressed. However, in accordance with NUREG-1757, Vol. 3, Appendix A.3 1.2.3, the NRC requires that the amount of financial assurance include a 25% contingency factor. This should be added to the cost estimate you provided, and that total amount be used in your financial assurance instrument. Also, please note that 10 CFR 30.35(e) requires that cost estimates be revised every 3 years, and if necessary, updated financial assurance be provided.

IBA Molecular commits to following the requirement for the 25% contingency factor, as well as recognizes the need to evaluate the cost estimates every three years.

8. Please use the NUREG-1757, Volume 3, guidance and models when establishing your financial assurance. In your letter, you stated that you plan to use a Surety Device. Guidance for Surety Bonds may be found in NUREG-1757, Vol. 3, Section 4.3.2.6 and Appendix A.9. Use of a Surety Bond will also require that you establish and submit a Standby Trust Agreement, for which guidance may be found in Section A.17. You are also required to provide the Certification of Financial Assurance, for which a model may be found in Appendix A.2.4.

Thank you for the information. IBA Molecular's Finance Department has been engaged to provide documentation of the appropriate financial instrument. Documentation will be forwarded to the NRC as required by NUREG-1757, Vol 3. Consideration is currently being given to using a letter of credit.

We appreciate your assistance with this transaction. If you have any additional questions about this accelerator RAM license application, please contact me at (424) 206-2480, or my assistant, Jim Kostka, RAM License Administrator, at (202) 207-5437.

Sincerely,



David W. Pellicciarini, CHP  
Vice President, Regulatory Affairs and EH&S  
IBA Molecular North America, Inc.

CC: Brad Richardson, Kansas City Site RSO  
Jim Kostka, RAM License Administrator