

P-7  
MS-16



October 7, 2013

Nuclear Regulatory Commission

Attn: Thomas Thompson

03032974

**RE: Request for Additional Information, Mail Control No. 581297, Lic. No. 45-25221-01MD**

Dear Mr. Thompson,

This letter is in response to your request for more information, 9/5/13. Please find below, the four requested items in italics, followed by and IBA response to each.

1. *Please clarify your response to item 6 of the NUREG-1556, Vol. 13 , Appendix C checklist. You have indicated that RAD workers may access restricted areas and handle RAM under indirect supervision, however, NRC expects that all use of byproduct materials be under the supervision of an authorized user. That does not necessarily mean physical presence but the activities must remain under supervision.*

IBA Molecular agrees and commits to all licensed activities being under the supervision of an authorized nuclear pharmacist.

2. *Also in item 6 of the checklist you indicate that you may open unused generator packages that are incoming and may be re-distributed. Please note that if packaging or labeling is altered in any way then this distribution may not be considered re-distribution. Please confirm that packages designated for re-distribution will not be altered in any way.*

IBA confirms that packages designated for re-distribution will not be altered in any way.

3. *In your response to Item 8.11.1 of NUREG-1556, Vol. 13 it is unclear if you are requesting authorization to receive sealed sources from customers that are no longer needed and therefore acting as a broker in facilitating disposal of the sealed sources. Please clarify if you are requesting to take possession of sealed sources for the purpose of acting as a broker in their disposal. If you are asking only to provide a service of preparing and packaging the sealed sources, but not taking possession, please indicate so*

IBA does not intend to act as a broker for disposal. IBA will only accept possession of sealed source that were originally supplied by IBA.

4. *Please note that although you have provided detailed emergency procedures and safe opening procedures we normally do not tie specific procedures to your license since you have already indicated you have developed and implemented the procedures on the checklist in Appendix C of your application.*

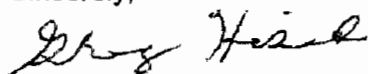
Rec'd in LAT 10/28/2013

581297  
NMSS/RGN1 MATERIALS-002

Noted and thank you for the information.

We appreciate your assistance with this. If you have any questions or need further information, please do not hesitate to contact me at (518) 755-7465 or [Gregory.hisel@ibamolecular.com](mailto:Gregory.hisel@ibamolecular.com).

Sincerely,

A handwritten signature in cursive script, appearing to read "Greg Hisel".

Gregory S. Hisel, CHP  
Director of Health Physics  
IBA Molecular North America, Inc.