From:	Lawyer, Dennis
To:	bill.galdenzi@boehringer-ingelheim.com
Subject:	Boehringer Ingelheim Pharm, Inc, Request for Additional Information Concerning Application for a License Renewal, Control 585381
Date:	Thursday, January 08, 2015 8:38:00 AM

Dear William Galdenzi,

This is in reference to your application dated November 20, 2014, requesting for renewal to Nuclear Regulatory Commission License No. 06-19183-01, Docket No. 03017101. In order to continue our review, we need the following additional information:

1. 10 CFR 30.35 requires that licensees authorized to possess and use unsealed licensed material with a half-life greater than 120 days in quantities greater than those described in 10 CFR 30.35(a) must submit decommissioning funding plan (DFP) in any new or renewal application. It is noted that you had performed the DFP cost estimate on March 19, 2014. Please confirm that this cost estimate is still accurate and may be used for this renewal, or submit updated DFP. If the DFP cost estimate is greater than your current certification of financial assurance, you must submit a revised financial assurance instrument in the prescribed amount of the cost estimate. Please follow closely the recommended wording for financial assurance mechanisms found Appendix A to Volume 3 of NUREG-1757.

2. In the objective of the Radiation Safety Committee (RSC) section, you give the duties and responsibilities of the RSC to include revising the program and procedures in accordance with Section 1 and 8.7.2 of NUREG-1556, Volume 11, "Program-Specific Guidance About Licensees of Broad Scope." In Section 8.7.2, it states for the licensee to describe the responsibilities of the RSC including the implementation of program and procedural changes, and audit of licensed operations to determine compliance. These two items did not appear have been as a RSC responsibility. Please state that the RSC is responsible to implement program and procedural changes, and perform audit of licensed operations to determine compliance.

3. Your application appears to request additional flexibility to make some procedure changes as described in Section 8.7.2 of NUREG-1556, Volume 11. It does not appear that you have provided a description of the process for procedure and program review and approval, including documentation of the specific change. NUREG-1556, Volume 11, states that the minimum documentation shall state the reason for the change and to summarize the radiation safety matters that were considered prior to approval of the change. Please provide a description of the process for procedure and program review and approval, including documentation of the specific change.

4. Your application states that the RSC approves uses by reviewing a formal radiation safety protocol. The application did not appear to state criteria for new users. NUREG-1556, Volume 11, Section 8.7.2 states to submit the criteria used by the RSC for approving new users and new uses. Please submit the criteria used for approving new uses and new users. You may wish to review the "response from applicant" portion of Section 8.9 of NUREG-1556, Volume 11 before responding.

5. In your application Section 8, Training, states that training will comply with the requirements specified in Appendix J of NUREG-1556, Volume 7. This does describe the frequency of training and the topics for training. However, it does not describe what groups of workers obtain this training, the qualifications of instructors, method of training, or method for assessing the success of the training. Please describe the groups of workers obtaining this training, the qualification of instructors, method of training, or method for assessing the success of training. Additionally, please describe other classes of workers and ancillary personnel like security and janitorial personnel.

6. Section 9 of your application describes your facility. As stated in Section 8.9 of NUREG-1556, Volume 11, applicants should provide sample diagrams. Areas where radioactive materials may become airborne, the sample diagrams should include descriptions of ventilation systems. For special application facilities, such as your radiosynthesis laboratory, you will need to specify their locations and special considerations that your RSC used in authorizing byproduct material use. Describe your procedures for control, review, and approval of significant facilities or equipment modifications. Please provide this information.

7. NUREG-1556, Volume 11, Section 8.10.3 states for the applicant to describe administrative procedures to assure control of procurement and use of byproduct material and describe administrative controls and provisions relating to materials control, accounting, and security. Your application states that you will manage material receipt and accountability in accordance with Section 8.10.2 of NUREG-1556, Volume 11 which does not describe procedures and has a typographical error to the wrong section number. Please describe administrative procedures to assure control of procurement and use of byproduct material and describe administrative controls and provisions relating to materials control, accounting, and security. You may refer to Appendix P of NUREG-1556, Volume 11 for the procurement and use portion of the procedures.

8. NUREG-1556, Volume 11, Section 8.10.7 states to submit your leak test procedures. You application did not include leak test procedures. As an alternative, you may state, “We will implement the model leak test program published in Appendix T of NUREG-1556, Volume 11, “Program-Specific Guidance About Licensees of Broad Scope.”

9. Your application states that you dispose of radioactive waste in accordance with Section 8.11 of NUREG-1556, Volume 11, which does not describe procedures. As stated in Section 8.11 of NUREG-1556, Volume 11, please provide procedures for waste collection, storage, and the disposal by any of the authorized methods described in this section. You may use the sample procedures in Appendix V of NUREG-1556, Volume 11, but please be specific to which sections of these procedures you are following.

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office (Address below) and refer to Mail Control No. 585381. If you have technical questions regarding this letter, please call me at (610) 337-5366.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We
strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please note that you may not reply to this letter by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

Region 1 Office Mailing Address: Licensing Assistance Team, US Nuclear Regulatory Commission Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406-2713.

Dennis Lawyer
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Material Safety
610-337-5366
610-337-5269 (F)