

From: [Lawyer, Dennis](#)
To: [Paradiso, Joseph](#)
Subject: Alexion Pharmaceuticals, Inc., Request for Additional Information Concerning Application for a License Amendment, Control 594704, License No. 06-28799-01, Docket No. 03032976
Date: Tuesday, May 16, 2017 9:37:00 AM

Dear Mr. Paradiso,

This is in reference to your letter dated May 4, 2017, requesting for amendment to Nuclear Regulatory Commission License No. 06-28799-01, Docket No. 03032976. In order to continue our review, we need the following additional information:

1. We currently list Stephen Uden, M.D. as the NRC management contact. Please have Dr. Uden sign that he concurs with the amendment request and the commitments provided.
2. Your commitment to training was not clear. You stated that you train all workers in accordance with NUREG-1556 and its requirements and the requirements of Appendix H, J, and K.. etc. However, you did not state which volume that you would train all workers. Additionally, you only need to train personnel as stated in the Laboratory Animal section of Appendix H. Please state that you will train personnel handling laboratory animals as stated in the Laboratory Animals section of Appendix H of NUREG-1556, Volume 7, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope." You will additionally train them as stated in Alexion's Institutional Animal Care and Use Committee Protocols, Alexion's Radiation Safety Manual, and Appendix J and K of NUREG-1556, Volume 7.
3. You did not provide any information about the new Vivarium facility other than it is certified by the American Association for Laboratory Animal Science. Currently you have specific rooms authorized on the license but you did not specify if the vivarium was contained within these rooms or somewhere else. As stated in NUREG-1556, Volume 7, please provide a schematic of additional areas utilizing radioactive material, describe the facilities and equipment to be made at the vivarium where radioactive material will be used.
4. During the last NRC inspection, the inspector noted that some rooms used for radioactive material had been renumbered and one room had never been used. Please submit a correction for changes in configuration from the anticipated facility to the facility constructed. If desired, please request removal of any rooms where radioactive material was never used.

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. 594704. If you have technical questions regarding this letter, please call me at (610) 337-5366.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. 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 OR amendment request.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

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.

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