From:	Lawyer, Dennis
To:	Paradiso, Joseph
Subject:	Alexion Pharmaceuticals, Inc.,, Request for Additional Information Concerning Application for a License Amendment, Control 591459
Date:	Monday, July 25, 2016 1:29:00 PM

Dear Mr. Paradiso,

This is in reference to your letter dated July 12, 2016, 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. You provided a survey of room D-1 of your facility. As stated in NUREG-1757 Volume 1, Please state the scan rates of the meters that was used for scan surveys in the room.

2. Prior to removal of a site from the license that used unsealed materials, 10 CFR 30.35(g) and 30.51 require that you submit to the NRC certain records. Please submit the following records, or explain why such records are not applicable.

    a. for unsealed materials with half-lives greater than 120 days, records for disposal made pursuant to 10 CFR 20.2002 (alternate disposal procedures, including burial authorized prior to January 28, 1981), 20.2003 (disposals to the sanitary sewerage system), 20.2004 (incineration of wastes), 20.2005 (disposal of specific wastes including liquid scintillation cocktail and animal tissue), and 20.2103(b)(4), evaluations of effluent releases.

    b. records important for decommissioning as described in 30.35(g). Examples of such records include but are not limited to: records of contamination, identifying the radionuclides, quantities and concentrations; as-built drawings and modifications of structures and equipment in restricted areas and locations of inaccessible contamination such as buried pipes; a single list, updated at least every 2 years, of areas to which access is limited for the purpose of radiation protection (restricted areas); and records related to the provision of financial assurance.

3. You provided a survey of room D-1 of your facility. However, this facility was added to the license on August 14, 2000. The use of D-1 was not added to the license until December 10, 2009. According to the renewal application dated March 19, 2003 the following rooms appear to have been used: D2, D-30, G-3. In a letter dated March 19, 2003, material was moved from G-3 to G-1. The letter stated that they would submit a survey of G-3, when they wanted it to be removed from the license. In a letter dated October, 3, 2005 a room named LAB 139-A was added. This room may have been only used for the irradiator and thus you just need to state that no unsealed material was used in the room. In the renewal application dated October 27, 2009 it stated material was used in D-1, D-2, D-30 and G-3. In order to release this facility, please provide surveys demonstrating the areas may be release for Rooms D-2, D-30, G-2, G-3, and Lab 139-A or explain why surveys are not needed.

4. Please certify that all licensed radioactive material have been removed from 352 Knotter Drive, Cheshire, Connecticut.

5. 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. 591459. 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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