

From: [Lawyer, Dennis](#)
To: kv@preludetx.com
Cc: [Leonard, Jessica](#)
Subject: Prelude Therapeutics Incorporated, Request for Additional Information Concerning Application for a License Amendment, Control 601936, License No. 07-35398-01, Docket No. 03039018
Date: Monday, January 08, 2018 2:11:00 PM

Dear Dr. Vaddi,

This is in reference to your letter dated December 1, 2017, requesting for amendment to Nuclear Regulatory Commission License No. 07-35398-01, Docket No. 03039018. In order to continue our review, we need the following additional information:

1. You state in section 3.5 of your report that wipe data was printed in units of cpm and dpm/100cm² (surface activity) as seen in the MicroBeta printouts in Attachments A and B. However, the printout data was not included in these attachments. Please provide the individual count data from the wipes. Please include any quality assurance printouts for any daily checks associated with the MicroBeta.
2. Please confirm that the only area of use was the biology lab. Please provide survey data of any other areas of use such as waste storage rooms.
3. In your application dated December 23, 2016, you stated that you would dispose of material in the sanitary sewer. It is not clear that the disposal area was surveyed. Please provide surveys or state which wipes were performed on drains used to dispose of liquid material.
4. Prior to termination of a license, 10 CFR 30.35(g), 30.36(k)(4) and 30.51 require that you submit certain records to the NRC. As you are decommissioning a facility, please submit the following records associate with the facility, or explain why such records are not applicable to your licensed activities.
 - 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.

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. 601936. 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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