From: Tran, Frank
To: Todd Hockemeyer
Subject: Request for additional information regarding NRC license application for POINT Biopharma U.S. Inc.
Date: Wednesday, December 23, 2020 9:03:00 PM

Dear Mr. Hockemeyer:

This refers to your application for a NRC license for research and development and our discussion via telephone today, December 22, 2020.

We have reviewed your NRC license application dated August 28, 2020 in accordance with the NRC licensing guidance and NUREG-1556, Volume 7, Revision 1. As discussed with you about the readiness for a pre-licensing site visit as required by the NRC for a new license application, you stated that the proposed site is still under construction and the facility and equipment may be ready for a visit via onsite or virtual in early of 2021. You will notify us when you are ready for the visit.

Based on our review and the discussion, we will need the following information.

1. Provide the statement “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’ We reserve the right to upgrade our survey instruments as necessary. Survey instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration.”

2. Provide the statement “We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times. Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 3 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer’s name and model numbers, and the date of the inventory.”

3. Provide the statement “We will develop, implement, and maintain procedures for safe use, security and emergencies.”

4. Provide the statement “We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”

5. Provide the statement “Leak tests for sealed sources will be performed at the intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Devices registration certificate. Leak tests will be analyzed by an organization authorized by the NRC or an Agreement State to provide leak testing

services to other licensees. Leak tests may be collected by the licensee, using the sealed source or plated foil manufacturer's (distributor's) and the leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services."

6. In Section 8.3 of the application, you provided that personnel working in or frequenting restricted areas will receive a general radiation training provided by Nuclear Education On-line (NEO) or equivalent. Please let us know the objectives or outlines of the training provided by the NEO. In addition, please provide the frequency of the training and how the training proficiency of an individual will be assessed.

7. Provide a facility diagram showing location where licensed material will be used; diagrams should be drawn to a specified scale, or dimensions should be indicated. In addition, please indicate the waste storage room.

8. Please confirm that you will use the decay-in-storage for wastes containing radionuclides with half-life less than or equal to 120 days and will transfer other radioactive waste to other authorized NRC or Agreement State licenses.

9. Please confirm that you will not acquire licensed material in a sealed source or device unless the source has been registered with the NRC pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

Please provide the response to the above in writing with signature by January 25, 2020. If you need additional time, please let me know. You could mail the response to NRC Region III, Materials Licensing Branch, 2443 Warrenville Road, Suite 210, Lisle, IL 60532 or fax to 630-515-1078. To facilitate proper mail handling in our office, please reference Mail Control No. 621132 in the cover letter.

If you have any questions, please contact me at 630-829-9623 or reply to this email.

Thank you,

Frank Tran
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NRC Region III/Division of Nuclear Materials Safety
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