



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

September 8, 2022

Michael Abel, M.S., Ph.D., CHP
Radiation Safety Officer
POINT Biopharma USA Inc.
4850 W. 78th St.
Indianapolis, IN 46268

SUBJECT: AMENDMENT NO. 05 TO RADIOACTIVE MATERIALS LICENSE FOR POINT BIOPHARMA USA INC., U.S. NRC MATERIALS LICENSE NO. 13-35593-01

Dear Dr. Abel:

Enclosed is Amendment No. 05 to U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-35593-01 in accordance with the letters dated July 20, 2022 and August 31, 2022, both signed by Todd Hockemeyer, Executive Vice President.

Congratulations on your appointment as Radiation Safety Officer. Additional information, guidance and resources are available from the agency to assist you. This includes NUREG-1556, Volume 7, Rev. 1, February 2018, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," particularly including Appendix E, "Radiation Safety Officer Duties and Responsibilities," and Appendix H, "Sample Audit Program." This guidance document is available on the U.S. NRC website at: <https://www.nrc.gov/docs/ML1806/ML18065A006.pdf>

In addition to identifying your appointment as Radiation Safety Officer, the license has also been amended to reflect:

- your designation as an Authorized User; and
- the designation of Todd Hockemeyer as Alternate Radiation Safety Officer.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC Region III office at (630) 829-9887 so that appropriate corrections or answers may be provided.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (CFR) Section 51.22(c).

You will be periodically inspected by the U.S. NRC. Failure to conduct your program in accordance with U.S. NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with U.S. NRC will result in enforcement action against you. This could include issuance of a notice of violation; or imposition of a civil penalty; or an Order suspending, modifying, or revoking your license as specified in the U.S. NRC Enforcement Policy. Since serious consequences to employees and the public can result

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

M. Abel

-2-

from failure to comply with U.S. NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance that U.S. NRC expects of its licensees.

The U.S. 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 the U.S. NRC's safety culture website at <https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. I 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 U.S. NRC-regulated activities.

The U.S. NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through the U.S. NRC's ADAMS, the U.S. NRC's electronic document system. Pursuant to U.S. NRC's RIS 2005-31 and in accordance with 10 CFR §2.390 of the U.S. NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the U.S. NRC's Generic Communications webpage under "Regulatory Issue Summaries" at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>, and the link for frequently asked questions regarding protection of security-related sensitive information may be located at <https://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the U.S. NRC Public Document Room or from the U.S. NRC's ADAMS, accessible from the U.S. NRC website at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-39229
License No.: 13-35593-01

Enclosure: Amendment No. 05 to U.S. NRC Materials License No. 13-35593-01