

## UNITED STATES NUCLEAR REGULATORY COMMISSION

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

September 15, 2022

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

## SUBJECT: CORRECTED COPY TO 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 a corrected copy to Amendment No. 5 to your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-35593-01, following receipt of your e-mail dated September 13, 2022, in which you identified an apparent error appearing in Item 6, Subpart O, of your license.

Following a review, Item 6, Subpart O, has been corrected to identify the authorized radionuclide as Ytterbium-177.

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 we may provide appropriate corrections and answers.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 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 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 the 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 U.S. NRC's safety culture Web site at <a href="https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html">https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html</a>. 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.

In accordance with 10 CFR 2.390 of the U.S. NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure 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 <a href="https://www.nrc.gov/reading-rm/adams.html">https://www.nrc.gov/reading-rm/adams.html</a>.

Sincerely,

Jason M. Kelly, MPH Health Physicist Materials Licensing Branch

Docket No.: 030-39229 License No.: 13-35593-01 Control No.: 631905

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