



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

March 10, 2021

Todd Hockemeyer
Radiation Safety Officer
POINT Biopharma U.S., Inc.
4850 W. 78th St.
Indianapolis, IN 46268

SUBJECT: NEW RADIOACTIVE MATERIALS LICENSE FOR POINT BIOPHARMA U.S.,
INC., NRC LICENSE NO. 13-35593-01

Dear Mr. Hockemeyer:

Enclosed is your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-35593-01, in accordance with your new license application.

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* (CFR) Section 51.22(c).

Please be advised that your license expires at the end of the day, in the month and year stated in the license. Unless your license has been terminated, you must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations including 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations;" 10 CFR Part 20, "Standards for Protection against Radiation;" and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When an authorized user (AU) or Radiation Safety Officer (RSO) permanently discontinues performance of duties under the license or has a name change; or
 - b. When the mailing address listed on the license changes.
3. In accordance with 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license;

- b. If you decide not to acquire or possess and use authorized material; or
 - c. When no principal activities under the license have been conducted for a period of 24 months.
4. Request and obtain a license amendment before you:
- a. Change Radiation Safety Officers;
 - b. Possess radioactive material in excess of the amount, radionuclide, or form authorized on the license;
 - c. Add or change the areas of use or address(es) of use identified in the license application or on the license; or
 - d. Change the name or ownership of your organization.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 60 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with 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 NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with 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 NRC expects of its licensees.

The 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 NRC's safety culture Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly 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 NRC-regulated activities.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public

Document Room or from the NRC's ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Frank P. D. Tran
Health Physicist
Materials Licensing Branch

Docket No.: 030-39229
License No.: 13-35593-01
Control No.: 621132

Enclosures:

1. License No. 13-35593-01
2. NUREG-1556, Volume 7, Revision 1: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/index.html>
3. Title 10 of the *Code of Federal Regulations* (10 CFR): <https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html>