U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 3

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated May 20, 2021,	4. Expiration Date: March 31, 2036
1. POINT Biopharma USA Inc. 2. 4850 W. 78th St. Indianapolis, IN 46268	3. License No.: 13-35593-01 is amended in its entirety to read as follows:	5. Docket No.: 030-39229 Reference No.:

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Fluorine-18	A. Liquid (non-volatile)	A. 1 curie total	A. For use in calibration and checking of the licensee's instruments.
B. Copper-64	B. Liquid (non-volatile)	B. 1 curie total	B. For research and development as defined in 10 CFR 30.4, including radioactive isotope labeling and calibration and checking of the licensee's instruments.
C. Gallium-68	C. Liquid (non-volatile)	C. 100 millicuries total	C. Same as Item No. 9.B.

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D. Lutetium-177	D. Solid or Liquid (non-volatile,)	D. 500 curies total	D. For research and development as defined in 10 CFR 30.4, including radioactive isotope labeling and calibration and checking of the licensee's instruments. For manufacturing, processing, and packaging of radiopharmaceuticals and/or radiochemicals for which the FDA has accepted an Investigational New Drug (IND) application, in accordance with the IND and with 10 CFR 32.72.
E. Ytterbium-175	E. Solid or Liquid (non-volatile,)	E. 2 curies total	E. For possession as radioactive waste incidental to the processing and purification of Lu-177 radionuclide listed in Item 6.D.
F. Actinium-225	F. Solid or Liquid (non-volatile,)	F. 1 curie total	F. Same as Item No. 9.B.
G. Barium-133	G. Sealed Sources	G. 30 millicuries total	G. For use as calibration and/or reference standards.
H. Cesium-137	H. Sealed Sources	H. 30 millicuries total	H. For use as calibration and/or reference standards.
I. Cobalt-57	I. Sealed Sources	I. 30 millicuries total	I. For use as calibration and/or reference standards.
J. Germanium-68	J. Sealed Sources	J. 30 millicuries total	J. For use as calibration and/or reference standards.
K. Any byproduct material with Atomic Numbers 3 through 83	K. Sealed Sources	K. 30 millicuries per source and 350 millicuries total	K. For use as calibration and/or reference standards.

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L. Technetium-99m	L. Liquid	L. 1 curie total	L. For research and development as defined in 10 CFR 30.4, including calibration and checking of the licensee's instruments and other equipment.

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CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at: 4850 W. 78th St., Indianapolis, Indiana, 46268.

11. The Radiation Safety Officer (RSO) for this license is Todd Hockemeyer.

12. Licensed material shall only be used by, or under the supervision of, Todd Hockemeyer.

13. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

14. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

15. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months, or at such other intervals as specified.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

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D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

E. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

G. Analysis of leak test samples and/or contamination shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is authorized to collect leak test samples but not perform the analysis.

H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for three years.

16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for three years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

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17. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:

    A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

    B. A record of each such disposal permitted under this license condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

18. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

19. Notwithstanding 10 CFR 32.72(a)(2), the licensee is authorized to prepare radioactive drugs, in accordance with an accepted FDA IND application protocol, and distribute them to medical use licensees in accordance with 10 CFR 32.72.

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20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those statements, representations, and procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence impose on the licensee requirements that are more restrictive than or in addition to the regulations.

A. Letter dated August 26, 2020 (ML20248H432)
B. Letter dated February 18, 2021 (ML21053A262)
C. Letter dated March 2, 2021 (ML21061A185)
D. Application dated July 7, 2021 (ML21119A011)
E. Letter dated October 4, 2021 (ML21277A352)
F. Letter dated May 20, 2021 (ML21160A110)
G. Letter dated November 29, 2021 (ML21334A194)

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Bryan A. Parker

Digitally signed by Bryan A. Parker
Date: 2021.12.01 14:24:45 -05'00'

Date: December 1, 2021

By: _____

Bryan A. Parker
Region III