

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 1. Sigma Aldrich MFG LLC 2. 3050 Spruce St. St. Louis, MO 63103		In accordance with letter dated February 27, 2020. 3. License number: 24-26445-01 is amended in its entirety to read as follows:	4. Expiration Date: December 31, 2023 5. Docket No.: 030-32903 Reference No.: 030-36554
6. Byproduct, source, and/or special nuclear material A. Iodine-125 B. Phosphorus-32	7. Chemical and/or physical form A. Any Except Sealed Sources B. Non-volatile	8. Maximum amount that licensee may possess at any one time under this license A. 500 millicuries total B. 5 millicuries total	9. Authorized use A. To be used in the manufacture of radiolabeled peptides and proteins for distribution to persons authorized to receive the licensed material under the terms and conditions of a specific license issued by the Commission or an Agreement State. Pursuant to 10 CFR 32.71, the licensee is authorized to distribute in-vitro kits containing prepackage units to persons generally licensed pursuant to 10 CFR 31.11, or equivalent provisions of the regulations of an Agreement State. B. For analytical testing of biochemical products.

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SUPPLEMENTARY SHEET**

License Number

24-26445-01

Amendment No. 31

Docket or Reference Number

030-32903

030-36554

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| 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 |
| C. Carbon-14 | C. Calibration and Standard Reference Sources (Eckert & Ziegler Isotope Products, Model Drawing No. 2500) | C. 225 nanocuries per source and 67.5 microcuries total | C. For possession and storage incident to distribution MVP ICON ATP Calibrator Set in accordance with the conditions of NRC Material License No. 24-35528-01E. |

CONDITIONS

10. A. Licensed material may be used at and/or distributed from the licensee's facilities located at 3050 Spruce St., St. Louis, Missouri, 63103.
B. Licensed material listed in Subitem No. 6.C. may be used at and/or distributed from the licensee's facilities located at 2425 S. 2nd St., St. Louis, Missouri, 63104.
11. Licensed material shall only be used by, or under the supervision of, the following individuals for the material and uses as indicated:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|-------------------------|------------------------------|
| April Bauer, Ph.D. | Phosphorous-32 and carbon-14 |
| Paul Klueh | Phosphorous-32 |
| John Nichols | Iodine-125 and carbon-14 |
| Jacob Philips | Phosphorous-32 and carbon-14 |
12. The Radiation Safety Officer (RSO) for this license is Robert E. Lee McVay.
13. This license does not authorize commercial distribution of licensed material to persons exempt from licensing pursuant to 10 CFR 30.18.
14. 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:

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- 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 3 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.
15. The licensee shall not use the licensed material in or on humans.
16. The licensee shall not use licensed material in field applications.
17. 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 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 are more restrictive than the regulations.
- A. Application dated June 25, 2013 excluding all references to Assistant Radiation Safety Officer (ML13177A409)
 - B. Letter dated January 30, 2014 (ML14035A338)
 - C. Letter dated April 3, 2014 (ML14111A436)
 - D. Letter dated June 1, 2014 (ML14162A235)
 - E. Letter dated May 27, 2015 (ML15224B316)
 - F. Letter dated October 24, 2016 (ML16306A272)
 - G. Letter dated January 17, 2017 (ML17020A076)

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- H. Letter dated January 25, 2017 (ML17026A068)
- I. Letter dated March 24, 2017 (ML17087A571)
- J. Letter dated May 22, 2017 excluding Item 3 (ML17151A376)
- K. Letter dated March 18, 2019 excluding MVP ICON procedures (ML19088A013)
- L. Letter dated February 27, 2020 (ML20064G854)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: March 12, 2020

By: _____

Frank P. D. Tran
Region 3