U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 52

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 January 22, 2019,	4. Expiration Date: July 31, 2022
1. Curium US LLC		5. Docket No.: 030-10801 Reference No.:
2. 2703 Wagner Place Maryland Heights, MO 63043	3. License No.: 24-04206-05MD is amended in its entirety to read as follows:	

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. Iodine-131	A. Sodium iodide capsules (NDA 16-517)	A. No possession authorized	A. The licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to 1) pursuant to Section 32.72 of 10 CFR Part 32, persons licensed pursuant to Sections 35.100, 35.200 and 35.300 of 10 CFR Part 35, or under equivalent licenses of Agreement States, or 2) commercial nuclear pharmacies.
B. Iodine-131	B. Sodium iodide liquid (NDA 16-515)	B. No possession authorized	B. Same as Item 9.A.

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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. Molybdenum-99/ Technetium-99m	C. Generators (Mallinckrodt, Model Ultra-Technekow Dry Top Eluting DTE and Ultra-Technekow V4 Generators (NDA 17-243))	C. No single generator to exceed 19.0 curies at the time of shipment.	C. The licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to 1) pursuant to Section 32.72 of 10 CFR Part 32, persons licensed pursuant to Section 35.200 of 10 CFR Part 35, or under equivalent licenses of Agreement States, or 2) commercial nuclear pharmacies.
D. Indium-111	D. Indium chloride liquid (NDA 20-314 and NDA 19- 841)	D. No possession authorized	D. The licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to 1) pursuant to Section 32.72 of 10 CFR Part 32, persons licensed pursuant to Sections 35.100 and 35.200 of 10 CFR Part 35, or under equivalent licenses of Agreement States, or 2) commercial nuclear pharmacies.
E. Thallium-201	E. Thallous chloride liquid (NDA 18-150)	E. No possession authorized	E. Same as Item 9.D.
F. Gallium-67	F. Gallium citrate liquid (NDA 18-058)	F. No possession authorized	F. Same as Item 9.D.
G. Iodine-123	G. Sodium iodide liquid (NDA 17-909 and NDA 17-910)	G. No possession authorized	G. Same as Item 9.D.
H. Xenon-133	H. Xenon gas (NDA 18-327)	H. No possession authorized	H. Same as Item 9.D.
I. Thorium-227	I. Thorium liquid conjugate	I. No possession authorized	I. For distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72.

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CONDITIONS

10. Each product distributed under this license shall not contain, as of the assay date (labeled size at calibration), more than the quantity of byproduct material listed in the table contained in Attachment I to the licensee's letter dated July 10, 2018 (ML18192A827).

11. The licensee may distribute material from the licensee's facilities located at 2703 Wagner Place, Maryland Heights, Missouri, 63043.

12. This license does not authorize possession or use of licensed material.

13. The Radiation Safety Officer (RSO) for this license is Manuel Diaz.

14. The licensee shall notify the U.S. Nuclear Regulatory Commission within thirty (30) days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug (IND)" for licensed material described in Items 6 and 7.

15. Any proposed change to shielding that will increase the radiation levels of the packaging shall be submitted to the NRC for review. Any proposed change to labeling that will cause a change to radioactive markings or labeled activity, other than position and increasing the size of symbols and wording, shall be submitted to NRC for review.

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16. Except as specifically provided otherwise in this license, the licensee shall manufacture, package, label and distribute licensed material described in Items 6 and 7 of this license and 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. Letter dated April 28, 2011 (ML111220490)
B. Letter dated February 7, 2012 (ML120390356)
C. Letter dated August 30, 2012 (ML12249A442)
D. Application dated March 5, 2013 (re: labeling revisions) (ML13067A379)
E. Letter dated July 11, 2013 (including attached SEC Form 8-K dated June 28, 2013) (ML13196A098)
F. Letter dated July 18, 2013 (ML13209A380)
G. Application dated July 24, 2014 (ML14209A090)
H. Application dated August 22, 2014 (re: RSO Delegation of Authority) (ML14239A329)
I. Letter dated October 27, 2014 (re: Figures 1 and 2 organization charts) (ML14322A098)
J. Letter dated March 16, 2015 (ML15077A494)
K. Letter dated September 21, 2015 (ML15265A509)
L. Letter dated February 22, 2016 (ML16076A387)

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M. Letter dated January 27, 2017 (ML17030A415)
N. Letter dated June 4, 2018 (re: d/b/a Curium) (ML16156A467)
O. Letter dated July 10, 2018 (re: Attachments D, G and I only) (ML18192A827)
P. Letter dated January 22, 2019 (ML19023A415)
Q. Letter dated April 2, 2019 (ML19093B579)

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date: APR 16 2019

By: _____
Bryan A. Parker
Region III