NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 8

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. Molecular NeuroImaging, LLC

2. 60 Temple Street
Suite 8A
New Haven, CT 06510

In accordance with email dated January 16, 2019.

3. License number: 06-30624-01 is amended in its entirety to read as follows:

4. Expiration Date: September 30, 2021

5. Docket No.: 030-35657
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. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 400 millicuries total	C. For any use permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.
D. Iodine-123	D. Any	D. 2 curies total	D. For research and development as defined in 10 CFR 30.4.
E. Fluorine-18	E. Any	E. 8 curies total	E. For research and development as defined in 10 CFR 30.4.
F. Chromium-51	F. Any	F. 10 millicuries total	F. For research and development as defined in 10 CFR 30.4.

MATERIALS LICENSE SUPPLEMENTARY SHEET

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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
G. Indium-111	G. Any	G. 50 millicuries total	G. For research and development as defined in 10 CFR 30.4.
H. Technetium-99m	H. Any	H. 500 millicuries total	H. For research and development as defined in 10 CFR 30.4.
I. Iodine-125	I. Any	I. 50 millicuries total	I. For research and development as defined in 10 CFR 30.4.
J. Bromine-76	J. Any	J. 50 millicuries total	J. For research and development as defined in 10 CFR 30.4.
K. Copper-64	K. Any	K. 50 millicuries total	K. For research and development as defined in 10 CFR 30.4.
L. Gallium-68	L. Any	L. 50 millicuries total	L. For research and development as defined in 10 CFR 30.4.
M. Zirconium-89	M. Any	M. 50 millicuries total	M. For research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 60 Temple Street, 8th and 9th floors, New Haven, Connecticut.

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11. Licensed material shall only be used by, or under the supervision of:

    A. Individuals permitted to work as authorized users in accordance with 10 CFR 35.13 and 10 CFR 35.14.

    B. The following individuals are authorized users for the material and medical uses as indicated:

Authorized User(M.D.,D.O.,etc.)	Material and Use
Indukala Doddamane, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.300
John P. Seibyl, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.300

    C. The following individuals are authorized users for nonmedical uses as indicated:

Authorized Users	Material and Use
Indukala Doddamane, M.D.	6.D. through 6.M. for research and development as defined in 10 CFR 30.4
John P. Seibyl, M.D.	6.D. through 6.M. for research and development as defined in 10 CFR 30.4

12. The Radiation Safety Officer (RSO) for this license is Indukala Doddamane, M.D.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee shall not use the licensed material authorized in Item 6.D. through 6.M. in or on humans.

15. This license does not authorize commercial distribution of licensed material.

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16. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

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 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.

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18. 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. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 March 25, 2011 (ML110880388)
B. Letter dated July 8, 2011 (ML111920393)
C. Application dated October 24, 2011 (ML112980515)
D. Letter dated October 27, 2011 (ML113010429)
E. Letter dated November 9, 2011 (ML113200022)
F. Letter dated August 4, 2014 (ML14223A609)
G. Letter dated May 8, 2015 (ML15153A224)
H. Letter dated May 24, 2016 (ML16159A109)
I. Letter dated August 24, 2016 (ML16238A347)
J. Letter dated April 9, 2019

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FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: April 11, 2019

By: Farrah C. Gaskins

Farrah Gaskins
Region 1