

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.

<p>Licensee</p> <p>1. Molecular NeuroImaging, LLC</p> <p>2. 60 Temple Street Suite 8A New Haven, CT 06510</p>		<p>In accordance with application dated August 17, 2021,</p>	<p>4. Expiration Date: February 28, 2037</p>
		<p>3. License No.: 06-30624-01 is renewed in its entirety to read as follows:</p>	<p>5. Docket No.: 030-35657 Reference No.:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Iodine-123</p> <p>E. Fluorine-18</p> <p>F. Chromium-51</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As Needed</p> <p>B. As Needed</p> <p>C. 400 millicuries total</p> <p>D. 2 curies total</p> <p>E. 8 curies total</p> <p>F. 10 millicuries total</p>	<p>9. Authorized use</p> <p>A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.</p> <p>B. For use in imaging and localization studies permitted by 10 CFR 35.200.</p> <p>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.</p> <p>D. For research and development as defined in 10 CFR 30.4.</p> <p>E. For research and development as defined in 10 CFR 30.4.</p> <p>F. For research and development as defined in 10 CFR 30.4.</p>

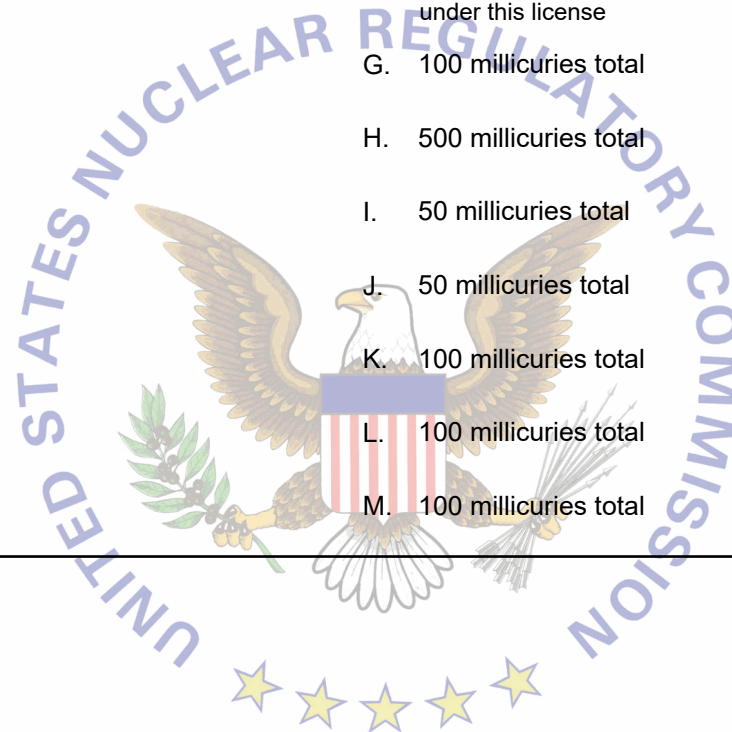
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 06-30624-01

Docket or Reference No.:
030-35657

Amendment No. 10

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. 100 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. 100 millicuries total	K. For research and development as defined in 10 CFR 30.4.
L. Gallium-68	L. Any	L. 100 millicuries total	L. For research and development as defined in 10 CFR 30.4.
M. Zirconium-89	M. Any	M. 100 millicuries total	M. For research and development as defined in 10 CFR 30.4.



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CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at: 60 Temple Street, 8th and 9th floors, New Haven, Connecticut, 06510
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:
- | <u>Authorized User (M.D., D.O., etc.)</u> | <u>Material and Use</u> |
|---|---|
| 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:
- | <u>Non-Medical Use</u> | <u>Material and Use</u> |
|--------------------------|--|
| 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. The licensee shall not use the licensed material authorized in Item 6.D. through 6.M. in or on humans.
14. This license does not authorize commercial distribution of licensed material.

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15. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
16. 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.
17. 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 in 10 CFR 30.35(d) for which decommissioning financial assurance is required.

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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 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. Application dated August 17, 2021 [ML21237A315]
- B. Letter dated January 12, 2022 [ML22014A081]
- C. Letter dated January 26, 2022 [ML22033A244]



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: February 7, 2022By: _____
Robin Elliott
Region 1