

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 03

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, 39, 40, and 70, 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 style="text-align: center;">Licensee</p> <p>1. Molecular NeuroImaging, LLC</p> <p>2. 60 Temple Street 8th Floor New Haven, Connecticut 06510</p>	<p>In accordance with application dated October 24, 2011,</p> <p>3. License number 06-30624-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date September 30, 2021</p> <hr/> <p>5. Docket No. 03035657 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>G. Indium 111</p> <p>H. Tc-99m</p> <p>I. Iodine 125</p> <p>J. Bromine 76</p> <p>K. Hydrogen 3</p> <p>L. Copper 64</p> <p>M. Gallium 68</p> <p>N. Zirconium 89</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>G. Any</p> <p>H. Any</p> <p>I. Any</p> <p>J. Any</p> <p>K. Any</p> <p>L. Any</p> <p>M. Any</p> <p>N. 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</p> <p>D. 2 curies</p> <p>E. 8 curies</p> <p>F. 10 millicuries</p> <p>G. 50 millicuries</p> <p>H. 500 millicuries</p> <p>I. 50 millicuries</p> <p>J. 50 millicuries</p> <p>K. 2 millicuries</p> <p>L. 50 millicuries</p> <p>M. 50 millicuries</p> <p>N. 50 millicuries</p>

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SUPPLEMENTARY SHEET**

License Number
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9. Authorized use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300, for which the patient can be released under the provisions of 10 CFR 35.75.
- D. through N. Research and development as defined in 10 CFR 30.4

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 60 Temple Street, 8th and 9th floors, New Haven, Connecticut.
11. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user, and/or authorized nuclear pharmacist in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

John P. Seibyl, M.D.

35.100; 35.200; 35.300

The following individuals are authorized users for research and development as defined in 10 CFR 30.4:

Users

Materials

John P. Seibyl, M.D.

6.D. through 6.N.

12. The Radiation Safety Officer for this license is John P. Seibyl, 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.

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14. This license does not authorize commercial distribution of licensed material.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. 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)

For the U.S. Nuclear Regulatory Commission

Original signed by Thomas K. Thompson

Date November 22, 2011 By _____

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406