

U.S. NUCLEAR REGULATORY COMMISSION

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>Licensee</p> <p>1. Yale University</p> <p>2. Environmental Health and Safety 135 College Street, First Floor Suite 100 New Haven, Connecticut 06510-2411</p>	<p>In accordance with the letter dated November 21, 2014,</p> <p>3. License number 06-00183-07 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date October 31, 2020</p> <hr/> <p>5. Docket No. 03038332 Reference No. 06-00183-03</p>
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<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. Germanium/Gallium-68 permitted by 10 CFR 35.500</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Sealed Sources (Siemens Medical Solutions USA, Inc. Model CS and LS Series)</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. 10 millicuries per source and 200 millicuries total</p>
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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. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at the PET Research Center, 801 Howard Avenue, First Floor Imaging Area, New Haven, Connecticut.
- 11. The Radiation Safety Officer for this license is Tammy Stemen, CHP.

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12. 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:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|-----------------------------------|-------------------------|
| Indukala Doddamane, M.D. | 35.100; 35.200; 35.500 |
| Albert J. Sinusas, M.D. | 35.100; 35.200; 35.500 |
| Raymond Russell, III, M.D., Ph.D. | 35.100; 35.200; 35.500 |
| Ming-Kai Chen, M.D., Ph.D. | 35.100; 35.200; 35.500 |
| Lawrence Saperstein, M.D. | 35.100; 35.200; 35.500 |
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 is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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15. 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 August 2, 2010 (except Radiochemistry/QC uses) [ML102160531]
 - B. Letter dated October 26, 2010 [ML103020262]
 - C. Letter dated July 29, 2011 [ML112210901]



For the U.S. Nuclear Regulatory Commission

Date February 10, 2015

By

Original signed by Penny Lanzisera

Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406