

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. Indiana University Health Arnett Hospital</p> <p>2. 5165 McCarty Ln. Lafayette, IN 47905</p>		<p>In accordance with letter dated February 13, 2018.</p> <p>3. License number: 13-32535-02</p>	<p>4. Expiration Date: November 30, 2026</p> <p>5. Docket No.: 030-37189 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. Yttrium-90 permitted by 10 CFR 35.1000</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Microspheres (Sirtex Wilmington LLC, Sirtex Medical Limited, or ANSTO Radiopharmaceuticals and Industrials, Model SIR-Spheres)</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. 500 millicuries total</p> <p>D. 1 curie 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 medical use permitted by 10 CFR 35.1000 in Sirtex Medical Limited SIR-Spheres microspheres therapy deliver systems.</p>

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-32535-02

Docket or Reference Number
030-37189

Amendment No. 13

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 5165 McCarty Ln., Lafayette, Indiana, 47905.
11. The Radiation Safety Officer (RSO) for this license is Joshua A. Nepute, M.D.
12. 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> |
|--|---|
| Rodney A. Dunseath, D.O. | 10 CFR 35.100, 35.200, and 35.300 |
| Phyllis Martin-Simmerman, M.D. | 10 CFR 35.100, 35.200, and 35.300 |
| Jeffery S. Calhoon, M.D. | 10 CFR 35.100, 35.200, and 35.300 |
| Mark C. Arvin, M.D. | 10 CFR 35.100, 35.200, and 35.300 |
| Douglas M. Dunco, M.D. | 10 CFR 35.100, 35.200, and 35.300 |
| Paul E. Timperman, M.D. | 10 CFR 35.100, 35.200, and 35.300 |
| Daniel Makana Edwards, M.D. | 10 CFR 35.100, 35.200, 35.300 (limited to oral administration of sodium-iodide I-131), and 35.1000 (limited to yttrium-90 in SIR-Spheres therapy delivery system) |
| Neil Mascarenhas, M.D. | 10 CFR 35.100, 35.200, 35.300 (limited to oral administration of sodium-iodide I-131), and 35.1000 (limited to yttrium-90 in SIR-Spheres therapy delivery system) |
| Joshua A. Nepute, M.D. | 10 CFR 35.100, 35.200, 35.300, and 35.1000 (limited to yttrium-90 in SIR-Spheres therapy delivery system) |
| Imran Kazem, M.D. | 10 CFR 35.100 and 35.200 |

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13. 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 and applicable guidance updates for 10 CFR 35.1000 uses. 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 April 26, 2016 (ML16134A262)
 - B. Letter dated October 28, 2016 (ML16308A426)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: APR 16 2018

By: _____

Cassandra F. Frazier
Region 3