

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 11

MATERIALS LICENSE

Corrected copy

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, 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. Indiana University Health Arnett Hospital</p> <p>2. 5165 McCarty Lane Lafayette, IN 47905</p>	<p>In accordance with the letter dated June 15, 2015,</p> <p>3. License number 13-32535-02 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date May 31, 2016</p> <hr/> <p>5. Docket No. 030-37189 Reference No.</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. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Yttrium-90 as 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 as SIR-Spheres (Sirtex Wilmington LLC, Sirtex Medical Limited and ANSTO Radiopharmaceuticals and Industrials)</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</p> <p>D. Not to exceed 189 millicuries per vial, total possession not to exceed one curie</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. 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.

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- D. For medical use permitted by 10 CFR 35.1000 in Sirtex Medical Limited SIR-Spheres microspheres therapy deliver systems.

CONDITIONS

10. Licensed material shall be used at 5165 McCarty Lane, Lafayette, Indiana.
11. **The Radiation Safety Officer for this license is Joshua Nepute, M.D.**
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user 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

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. Cahoon, 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 the 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).
Neil Mascarenhas, M.D.	10 CFR 35.100, 35.200, 35.300 (limited to the oral administration of sodium iodide I-131) and 35.1000 (limited to yttrium-90 in SIR-spheres therapy delivery system).

13. 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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14. 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 28, 2006;
- B. Letters dated June 6, 2006, July 9, 2006, August 2, 2006, April 23, 2013, August 8, 2013, November 11, 2013, May 19, 2014 (received June 23, 2014) February 19, 2015 (received May 19, 2015), **June 15, 2015 (received July 22, 2015)**; and,
- C. Facsimile letters dated October 10, 2008, and October 20, 2008.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 19 2015

By

Toyé L. Simmons
Materials Licensing Branch
Region III