

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 49

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, 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. Indiana University Health LaPorte Hospital</p> <p>2. 1007 Lincolnway LaPorte, Indiana 46350-0250</p>	<p>In accordance with application dated February 24, 2014,</p> <p>3. License No. 13-15151-01 is renewed in its entirety to read as follows:</p> <p>4. Expiration Date: July 31, 2024</p> <p>5. Docket No. 030-08653 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 (Sirtex Wilmington LLC, Sirtex Medical Limited and ANSTO Radio-pharmaceuticals 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. 5 curies</p> <p>D. Not to exceed 189 millicuries per vial; total possession not to exceed 1 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.
- D. For medical use permitted by 10 CFR 35.1000 in Sirtex Medical Limited SIR-Spheres® microspheres therapy delivery systems.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 1007 Lincolnway, LaPorte, Indiana.

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11. The Radiation Safety Officer (RSO) for this license is James C. Hatten.
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:
- | <u>Authorized User</u> | <u>Material and Use</u> |
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| Hester Muller, M.D. | 10 CFR 35.100, 35.200 and 35.300. |
| Smari Thordarson, M.D. | 10 CFR 35.100, 35.200 and 35.300. |
| John E. DePersio, M.D. | 10 CFR 35.100, 35.200 and 35.300 (Oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries). |
| Krishna R. Pillai, M.D. | 10 CFR 35.100 and 35.200. |
| Syed I. Ali, M.D. | 10 CFR 35.100, 35.200, 35.300 (Oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries), and 35.1000 (limited to yttrium-90 in SIR-spheres® therapy delivery system). |
| Irfan Ahmad, M.D. | 10 CFR 35.100, 35.200 and 35.300 (Oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries). |
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 January 24, 2014; and
- B. Letters dated February 25, 2013 and August 13, 2014;
- C. Facsimile received May 22, 2013.

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date AUG 14 2014By 

Bryan A. Parker
Materials Licensing Branch
Region III