

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 style="text-align: center;">Licensee</p> <p>1. St. Mary Medical Center - Hobart</p> <p>2. 1500 S Lake Park Ave. Hobart, IN 46342</p>	<p>In accordance with letter dated August 05, 2024,</p> <p>3. License No.: 13-03459-03 is amended in its entirety to read as follows:</p>	<p>4. Expiration Date: January 31, 2026</p> <p>5. Docket No.: 030-31379 Reference No.:</p>
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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 500 millicuries total	C. For any use permitted by 10 CFR 35.300.
D. Any byproduct material permitted by 10 CFR 31.11	D. Prepackaged Kits	D. 3 millicuries total	D. For use in in-vitro studies.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-03459-03

Docket or Reference No.:
030-31379

Amendment No. 45

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
E. Yttrium-90 permitted by 10 CFR 35.1000	E. Microspheres (Sirtex Medical Pty Ltd., Model SIR-Spheres)	E. 296 millicuries per vial; 2 curies total	E. For use in permanent manual brachytherapy using the Sirtex Wilmington LLC Model SIR-Spheres yttrium-90 microspheres delivery system as permitted by 10 CFR 35.1000.
F. Yttrium-90 permitted by 10 CFR 35.1000	F. Microspheres (BWXT Medical, Ltd., Model TheraSphere)	F. 540 millicuries per vial; 4 curies total	F. For use in permanent manual brachytherapy using the BWXT Medical, Ltd. Model TheraSphere yttrium-90 microspheres delivery system as permitted by 10 CFR 35.1000.



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Amendment No. 45

CONDITIONS

10. A. Licensed material listed in Subitem Nos. 6.A. through 6.F. may be used or stored at the licensee's facilities located at 1500 S Lake Park Ave., Hobart, Indiana.
- B. Licensed material listed in Subitem Nos. 6.A. through 6.D. may also be used or stored at the licensee's facilities located at 300 W 61st Ave., Hobart, Indiana.
- C. Licensed material listed in Subitem Nos. 6.A. through 6.B may also be used or stored at the licensee's facilities located at 3545 Arbors Blvd., Portage, Indiana.
- D. Licensed material listed in Subitem Nos. 6.A. through 6.B may also be used or stored at the licensee's facilities located at 3800 St. Mary Drive, Valparaiso, Indiana.
11. The Radiation Safety Officer (RSO) for this license is Santosh K. Kar, MS.
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> |
|---|---|
| Samer Ajam, M.D. | 10 CFR 35.200 |
| Keith Atassi, M.D. | 10 CFR 35.200 |
| Janushi Dalal, M.D. | 10 CFR 35.100,10 CFR 35.200 |
| Joseph Danavi, M.D. | 10 CFR 35.200 |
| John W. Gustaitis, Jr., M.D. | 10 CFR 35.100,10 CFR 35.200,10 CFR 35.300 |
| Thomas M. Hoess, M.D. | 10 CFR 31.11,10 CFR 35.100,10 CFR 35.200 |
| Abdul Kawamleh, M.D. | 10 CFR 35.100,10 CFR 35.200 |
| Shawn R. Kenney, M.D. | 10 CFR 31.11,10 CFR 35.100,10 CFR 35.200 |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-03459-03

Docket or Reference No.:
030-31379

Amendment No. 45

Authorized User (M.D.,D.O.,etc.)Material and Use

A. Arif Khalil, M.D.

10 CFR 35.200

Akram Kholoki, M.D.

10 CFR 35.100,10 CFR 35.200

Sorin Lazar, M.D.

10 CFR 35.200

Jonathon T. Lee, M.D.

10 CFR 31.11,10 CFR 35.100,10 CFR 35.200

Alexander Lionberg, M.D.

10 CFR 35.200; 10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres and TheraSpheres)

Mary Nicholson, M.D.

10 CFR 35.100,10 CFR 35.200

Omar Obaid, M.D.

10 CFR 35.100,10 CFR 35.200

Charles-Lauwanga Okoro, D.O.

10 CFR 35.200

Harish Patlolla, M.D.

10 CFR 35.200

Anas Hakam Safadi, M.D.

10 CFR 35.200

Michele Semin, M.D.

10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131 in quantities of 33 millicuries or less)

Harish Shah, M.D.

10 CFR 35.100,10 CFR 35.200

Vijah P. Shah, M.D.

10 CFR 35.100,10 CFR 35.200

Justin Spackey, M.D.

10 CFR 35.100,10 CFR 35.200

Robert Woodburn, M.D.

10 CFR 35.300

Lingyun Xiong, M.D.

10 CFR 35.300 (limited to the oral administration of sodium iodide I-131 in quantities of 33 millicuries or less)

Kais J. Yehyawji, M.D.

10 CFR 35.100,10 CFR 35.200

Feng Zhang, M.D.

10 CFR 35.100,10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium iodide I-131 in quantities of 33 millicuries or less)

13. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all glass microspheres received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

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SUPPLEMENTARY SHEET**

License No.: 13-03459-03

Docket or Reference No.:
030-31379

Amendment No. 45

14. In accordance with letters dated December 19, 2017 (ML17353A894) and September 12, 2023 (ML23261C392), the licensee may make changes to its radiation safety program, as it relates to the use of yttrium-90 microspheres as permitted by 10 CFR 35.1000.
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 statements, representations, and 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 impose on the licensee requirements that are more restrictive than or in addition to the regulations.
- A. Application dated July 28, 2015 (ML15218A568)
 - B. Letter dated January 6, 2016 (ML16007A729)
 - C. Letter dated January 5, 2017 (ML17018A414)
 - D. Letter dated May 22, 2017 (ML17146B324)
 - E. Letter dated June 20, 2017 (ML17172A121)
 - F. Letter dated September 28, 2017 (ML17276B167)
 - G. Letter dated December 19, 2017 (ML17354A646)
 - H. Letter dated December 19, 2017 (ML17353A894)
 - I. Letter dated February 26, 2018 (ML18057A559)
 - J. Letter dated September 26, 2019 (ML19270H110)
 - K. Letter dated May 11, 2020 (ML20141L681)
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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-03459-03

Docket or Reference No.:
030-31379

Amendment No. 45

- L. Letter dated August 10, 2020 (ML20227A262)
- M. Letter dated September 9, 2020 (ML20260H261)
- N. Letter dated September 12, 2023 (ML23261C392)
- O. Letter dated October 12, 2023 (ML23286A131)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: September 3, 2024

By: _____

Jason M. Kelly, MPH, CPH
Health Physicist
Region III