

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. Elkhart General Hospital</p> <p>2. 600 East Blvd. Elkhart, IN 46515</p>	<p>In accordance with letter dated April 09, 2024,</p> <p>3. License No.: 13-18879-01 is amended in its entirety to read as follows:</p>	<p>4. Expiration Date: November 30, 2036</p> <p>5. Docket No.: 030-17305 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. 1 curie total	C. For any use permitted by 10 CFR 35.300.
D. Yttrium-90 permitted by 10 CFR 35.1000	D. Microspheres (Sirtex Wilmington LLC, Model SIR-Spheres)	D. 1 curie total	D. For use in permanent manual brachytherapy using Sirtex Wilmington LLC Model SIR-Spheres Yttrium-90 microspheres and delivery system permitted by 10 CFR 35.1000.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-18879-01

Docket or Reference No.:
030-17305

Amendment No. 72

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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>E. Yttrium-90 permitted by 10 CFR 35.1000</p> | <p>7. Chemical and/or physical form</p> <p>E. Microspheres (BWXT Medical Ltd., Model TheraSpheres)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>E. 2 curies total</p> | <p>9. Authorized use</p> <p>E. For use in permanent manual brachytherapy using BWXT Medical Ltd. Model TheraSphere Yttrium-90 microspheres and delivery system permitted by 10 CFR 35.1000.</p> |
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CONDITIONS

10. A. Licensed material shall be used or stored at the licensee's facilities located at 600 East Blvd., Elkhart, Indiana.
- B. Licensed material listed in Item No. 6.B. shall be used and stored at the licensee's facilities located at 303 S. Nappanee St., Suite B, Elkhart, Indiana.
11. The Radiation Safety Officer (RSO) for this license is Daniel J. Archambeault, M.S.
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:

Authorized User (M.D., D.O., etc.)

Material and Use

Nicholas Abel, M.D.

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium iodide I-131)

Syed I. Ali, 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 less than or equal to 33 millicuries), 10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres)

Michael Brendle, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Thomas Joseph Cellini, D.O.

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium iodide I-131)

Mary C. Dynes, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Luisito Gonzales, M.D.

10 CFR 35.200

Michael Grantham, 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)

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

Alphonse H. Harding, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Daniel Homuth, D.O.

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium iodide I-131)

Nazmul Huda, M.D.

10 CFR 35.200

David Isaacs, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Russell F. Johnson, M.D.

10 CFR 35.300 (limited to parenteral administration of radium-223 dichloride)

Sridevi Kanuri, 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)

Allison Marie Lamont, 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)

Wai Hung Lee, M.D.

10 CFR 35.200

Thomas Phillip Lowe, M.D.

10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium iodide I-131)

Charles Augustine Mathis, M.D.

10 CFR 35.200

Vigay Arvindkumar Mehta, M.D.

10 CFR 35.200

Russell B. Midkiff, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Pedro A. Miro, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Christine Marie O'Malley, M.D.

10 CFR 35.100, 10 CFR 35.200

Samir B. Patel, M.D.

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium iodide I-131)

Naila Qazi, M.D.

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)

Thomas Kang Rhee, M.D.

10 CFR 35.100, 10 CFR 35.200

Brian Schirf, M.D.

10 CFR 35.1000 (limited to yttrium-90 as Sir-Spheres and TheraSpheres)

Karl W. Schultz, M.D.

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

Alexander Tawadros, M.D.

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium iodide I-131)

Timothy Lyndon Tsai, M.D.

10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium iodide I-131)

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Authorized User (M.D., D.O., etc.)

Venu Vadlamudi, M.D.

Katrina Vanderveen, M.D.

Jonathan W. Weiss, M.D.

Material and Use

10 CFR 35.1000 (limited to yttrium-90 as Sir-Spheres and TheraSpheres)

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)

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300; 10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres)



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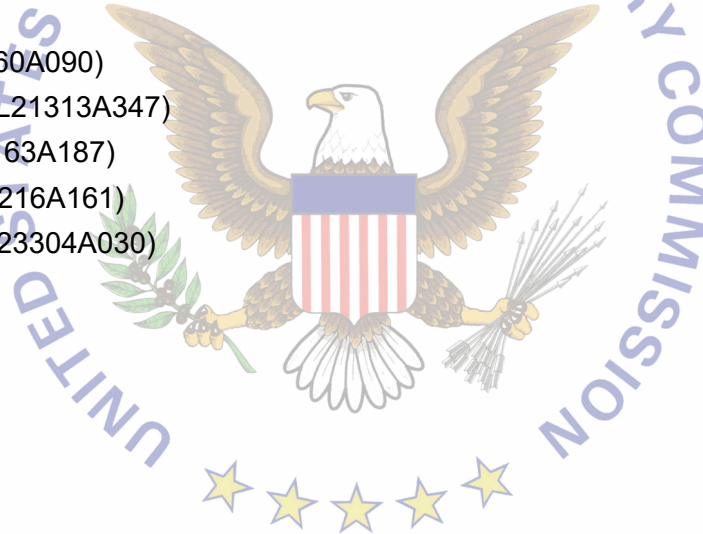
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13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those 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 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 impose on the licensee requirements that are more restrictive than or in addition to the regulations.

- A. Letter dated May 27, 2021 (ML21160A090)
- B. Letter dated November 2, 2021 (ML21313A347)
- C. Letter dated June 12, 2023 (ML23163A187)
- D. Letter dated August 1, 2023 (ML23216A161)
- E. Letter dated October 23, 2023 (ML23304A030)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: April 30, 2024By: _____
Jason M. Kelly, MPH, CPH
Health Physicist
Region III