

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.

Licensee 1. Indiana University Health Arnett Hospital 2. 5165 McCarty Ln. Lafayette, IN 47905		In accordance with letter dated June 08, 2023, 3. License No.: 13-32535-02 is amended in its entirety to read as follows:	4. Expiration Date: November 30, 2026 5. Docket No.: 030-37189 Reference No.:
6. Byproduct, source, and/or special nuclear material A. Any byproduct material permitted by 10 CFR 35.100 B. Any byproduct material permitted by 10 CFR 35.200 C. Any byproduct material permitted by 10 CFR 35.300 D. Yttrium-90 permitted by 10 CFR 35.1000	7. Chemical and/or physical form A. Any B. Any C. Any D. Microspheres (Sirtex Wilmington LLC, Sirtex Medical Limited, or ANSTO Radiopharmaceuticals and Industrials, Model SIR-Spheres)	8. Maximum amount that licensee may possess at any one time under this license A. As Needed B. As Needed C. 500 millicuries total D. 1 curie total	9. Authorized use A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100. B. For use in imaging and localization studies permitted by 10 CFR 35.200. 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. D. For medical use permitted by 10 CFR 35.1000 in Sirtex Medical Limited SIR-Spheres microspheres therapy deliver systems.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-32535-02

Docket or Reference No.:
030-37189

Amendment No. 18

- | | | | |
|---|---|--|---|
| <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 TheraSphere)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>E. Not to exceed 540 millicuries per vial; 4 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> |
|---|---|--|---|



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-32535-02

Docket or Reference No.:
030-37189

Amendment No. 18

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:

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

Material and Use

Mark C. Arvin, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.300

Jeffery S. Cahoon, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.300

Douglas M. Dunco, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.300

Rodney A. Dunseath, D.O.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.300

Daniel Makana Edwards, M.D.

10 CFR 35.100,10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium-iodide I-131); 10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres, and yttrium-90 as TheraSphere in physical presence of an authorized user who is authorized for yttrium-90 as TheraSphere)

Luke Gerges, D.O.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.300

Imran Kazem, M.D.

10 CFR 35.100,10 CFR 35.200

Phyllis Martin-Simmerman, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.300

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 13-32535-02

Docket or Reference No.:
030-37189

Amendment No. 18

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

Neil Mascarenhas, M.D.

Joshua A. Nepute, M.D.

Paul E. Timperman, M.D.

Erika J. Ugianskis, M.D.

Brandon W. Upp, D.O.

Material and Use

10 CFR 35.100, 10 CFR 35.200; 10 CFR 35.300 (limited to oral administration of sodium-iodide I-131); 10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres, and yttrium-90 as TheraSphere in physical presence of an authorized user who is authorized for yttrium-90 as TheraSphere)

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

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres)

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

13. In accordance with the letters dated October 28, 2016, April 25, 2023 and June 8, 2023, 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

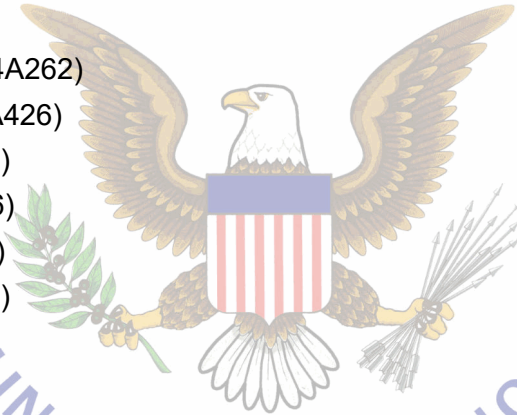
License No.: 13-32535-02

Docket or Reference No.:
030-37189

Amendment No. 18

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 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)
- C. Letter dated July 25, 2018 (ML18212A300)
- D. Letter dated April 25, 2023 (ML23125A006)
- E. Letter dated June 8, 2023 (ML23160A176)
- F. Letter dated July 14, 2023 (ML23198A068)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: July 21, 2023By: _____
Laura B. Cender
Region 3