

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. University of Michigan Health-West 2. 5900 Byron Center Ave. SW Wyoming, MI 49519		In accordance with letter dated April 07, 2023, 3. License No.: 21-12829-01 is amended in its entirety to read as follows:	4. Expiration Date: October 31, 2024 5. Docket No.: 030-02134 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 E. Yttrium-90 permitted by 10 CFR 35.1000	7. Chemical and/or physical form A. Any B. Any C. Any D. Microspheres (AEA Technology QSA GmbH, Model SIR-Spheres) E. Microspheres (BWXT ITG Canada, Inc., Model TheraSphere)	8. Maximum amount that licensee may possess at any one time under this license A. As Needed B. As Needed C. 1 curie total D. 296 millicuries per vial; 3 curies total E. 3 curies 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. D. For medical use in a Sirtex Medical Limited brachytherapy delivery system permitted by 10 CFR 35.1000. E. For medical use in a TheraSphere dose delivery system permitted by 10 CFR 35.1000.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 21-12829-01

Docket or Reference No.:
030-02134

Amendment No. 74

CONDITIONS

10. A. Licensed material listed in Item Nos. 6.A. through 6.E. shall be used at the licensee's facilities located at 5900 Byron Center Ave. S.W., Wyoming, Michigan 49519.
- B. Licensed material listed in Item Nos. 6.A. and 6.B. shall be used at the licensee's facilities located at 1915 W. Washington St., Suite 1, Greenville, Michigan 48838.
11. The Radiation Safety Officer (RSO) for this license is Dawn M. Edwards, 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

Christina Bakalis, M.D.

10 CFR 35.100,10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131), 10 CFR 35.1000 (limited to use of yttrium-90 TheraSpheres and yttrium-90 SIR-Spheres)

Kimberly A. Chaney, M.D.

10 CFR 35.100,10 CFR 35.200

Michael D. Koets, M.D.

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

Paul Kovack, D.O.

10 CFR 35.200

Kyle E. Pfeifer, M.D.

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

Suprotim Samaddar, D.O.

10 CFR 35.200

Matthew W. Sevensma, D.O.

10 CFR 35.100,10 CFR 35.200

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

Matthew A. Tiede, M.D.

Eric T. Walchak, D.O.

Material and Use

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300; 10 CFR 35.1000 (limited to use of yttrium-90 TheraSpheres and yttrium-90 SIR-Spheres)

10 CFR 35.100, 10 CFR 35.200

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 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. Letter dated June 24, 2014 (ML14178B486)
- B. Letter dated October 28, 2014 (ML14304A625)
- C. Letter dated January 8, 2014 and received January 13, 2015 (ML15013A469)
- D. Letter dated January 8, 2015 (ML15016A356)
- E. Letter dated February 23, 2015 (ML15062A622)
- F. Letter dated December 21, 2015 (ML15365A520)
- G. Letter dated October 27, 2016 (ML16302A408)
- H. Letter dated February 8, 2017 (ML17052A725)
- I. Letter dated October 24, 2017 (ML17299B290)
- J. Letter dated November 20, 2017 (ML17334B148)

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- K. Letter dated June 1, 2018 (ML18157A186)
- L. Letter dated September 24, 2018 (ML18269A296)
- M. Letter dated November 7, 2018 (ML18312A193)
- N. Letter dated July 11, 2019 (ML19199A340)
- O. Letter dated January 4, 2022 (ML22027A554)
- P. Letter dated March 25, 2022 (ML22084A064)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: June 12, 2023

By: _____

Colleen Carol Casey
Region 3