

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>Licensee</p> <p>1. MidState Medical Center</p> <p>2. 435 Lewis Avenue Meriden, CT 06451</p> | | <p>In accordance with letter dated December 19, 2024,</p> | <p>4. Expiration Date: December 31, 2038</p> |
| | | <p>3. License No.: 06-05686-02 is amended in its entirety to read as follows:</p> | <p>5. Docket No.: 030-01257 Reference No.: 06-30432-01</p> |
| <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 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 (BWXT Medical Ltd. (formerly BWXT ITG Canada, Inc.), Model TheraSphere®)</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. 2.2 curies total</p> <p>D. 1 curie total</p> | <p>9. Authorized use</p> <p>A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.</p> <p>B. For use in imaging and localization studies permitted by 10 CFR 35.200.</p> <p>C. For any diagnostic study or therapy procedure permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.</p> <p>D. TheraSphere® for permanent brachytherapy using delivery system as listed in the Sealed Source and Device Registry</p> |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 06-05686-02

Docket or Reference No.:

030-01257 06-30432-01

Amendment No. 64

CONDITIONS

10. A. Licensed material shall be used or stored at the licensee's facilities located at 435 Lewis Avenue, Meriden, Connecticut, 06451.
- B. Licensed material listed in Subitem No. 6.B. may be used or stored at the licensee's facilities located at the Wallingford Diagnostic Imaging Center, 863 North Main Street Extension, Wallingford, Connecticut, 06492.
11. A. The Radiation Safety Officer (RSO) for this license is Harry Hajedemos, M.D.
- B. The Associate Radiation Safety Officer (ARSO) for this license is George Pavlonnis, M.S. for 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, and 10 CFR 35.1000 (Yttrium-90 TheraSpheres) activities.
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 Users

Dylan Assael, M.D.

Anita Bourque, M.D.

James Choi, M.D.

Felicia Cuomo, M.D.

Holly M. Dey, M.D.

William Daniel Donovan, M.D.

Material and Use

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 the use of yttrium-90 TheraSpheres)

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

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

10 CFR 35.100, 10 CFR 35.200

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.100, 10 CFR 35.200

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 06-05686-02

Docket or Reference No.:

030-01257 06-30432-01

Amendment No. 64

Authorized Users

Nathaniel D. Dueker, M.D.

Thomas A. Fay, M.D.

Joel Gelber, M.D.

Alfred G. Gladstone, M.D.

Shahar Glomski, M.D.

Harry Hajedemos, M.D.

Kathryn Heaphy, M.D.

Guillermo R. Jimenez, M.D.

Phillip Kohanski, M.D.

Marcin Kolber, M.D.

Allan S. Kratzer, M.D.

Jason D. Mayo, M.D.

Frank M. Mele, M.D.

Kishna Patel, M.D.

Zenon Protopapas, M.D.

Stacy L. Spooner, M.D.

Jeffrey Takahashi, M.D.

Michael Talarico, M.D.

Material and Use

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

10 CFR 35.100, 10 CFR 35.200

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

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

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

10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300

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 the use of yttrium-90 TheraSpheres)

10 CFR 35.300

10 CFR 35.100, 10 CFR 35.200

10 CFR 35.100, 10 CFR 35.200

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

10 CFR 35.100, 10 CFR 35.200

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

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

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

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 06-05686-02

Docket or Reference No.:

030-01257

06-30432-01

Amendment No. 64

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit in 10 CFR 30.35(d) for which decommissioning financial assurance is required.
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 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 February 23, 2023, with attachments [ML23058A379]
 - B. Letter dated August 21, 2023, with attachments (excluding facility diagrams and equipment list for Whitney Imaging) [ML23237A265]
 - C. Letter dated October 24, 2023, with attachment [ML23319A193]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: January 8, 2025

By: _____

Jason vonEhr
Region 1