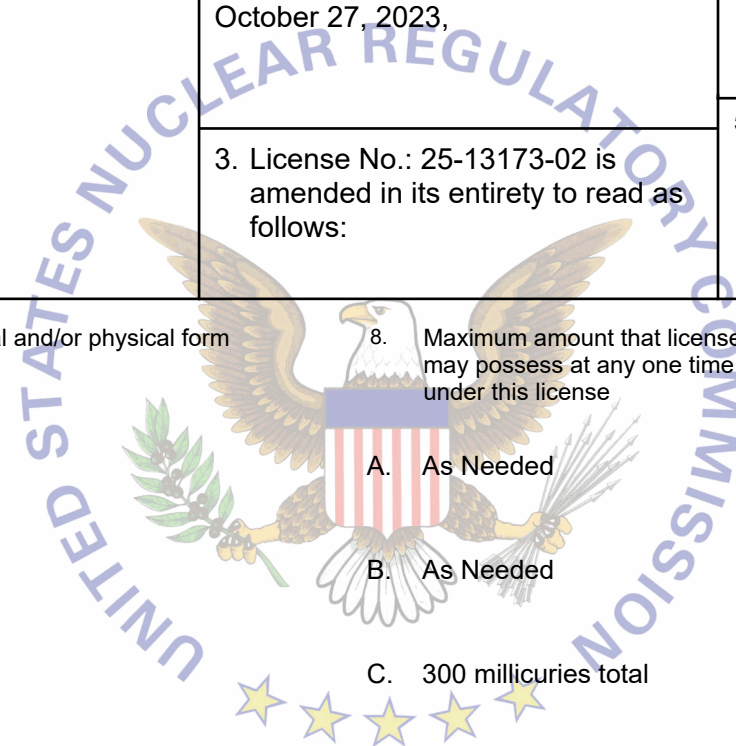


MATERIALS LICENSE

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.

| | | | |
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| <p>Licensee</p> <p>1. St. James Healthcare</p> <p>2. 400 South Clark Street P.O. Box 3300 Butte, MT 59702</p> | | <p>In accordance with letter dated October 27, 2023,</p> | <p>4. Expiration Date: January 31, 2024</p> |
| | | <p>3. License No.: 25-13173-02 is amended in its entirety to read as follows:</p> | <p>5. Docket No.: 030-12143 Reference No.:</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., Model TheraSphere Y-90 Glass Microsphere System)</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. 300 millicuries total</p> <p>D. 4 curies 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 use permitted by 10 CFR 35.300.</p> <p>D. For use in TheraSphere for permanent brachytherapy using delivery system as listed in the sealed source and device registry.</p> |



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 25-13173-02

Docket or Reference No.:
030-12143

Amendment No. 58

CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at 400 South Clark Street, Butte, Montana, 59702.
11. The Radiation Safety Officer (RSO) for this license is Jefferson Fairbanks, Ph.D.
12. Licensed material shall only be used by, or under the supervision of:
- A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists, 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> |
|---|--|
| Justin S. Clark, M.D. | 35.100; 35.200 |
| Jeffrey Gilroy, M.D. | Parenteral administration of unsealed byproduct material requiring a written directive |
| Peder E. Horner, M.D. | 35.100; 35.200; 35.1000 Y-90 TheraSphere |
13. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
14. 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 25-13173-02

Docket or Reference No.:
030-12143

Amendment No. 58

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 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. Application dated July 11, 2013 (ML13246A486 and ML13275A662)
- B. Letter dated January 12, 2014 with enclosures (ML14015A352)
- C. Letter dated January 28, 2022 with enclosures (ML22055A670)
- D. Letter dated September 27, 2023 with enclosures (ML23270B755)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: October 30, 2023By: _____
Roberto J. Torres
Region IV