

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. Avera St. Luke's dba Avera St. Luke's Hospital</p> <p>2. 305 South State Street Aberdeen, SD 57401</p>		<p>In accordance with letter dated September 21, 2020,</p>	<p>4. Expiration Date: November 30, 2025</p>
		<p>3. License No.: 40-18000-01 is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-13778 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. Cesium-137 permitted by 10 CFR 35.400</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed Sources (3M Health, Model 6500 Series; Amersham-Buchler GmbH & Co. KG (Medi-Physics, Inc. d/b/a GE Healthcare), Model CDC.N2 [Product codes CDCS.S16-18, CDCS.S4, S5, S40])</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. 400 millicuries total</p> <p>D. 940 millicuries 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 any manual brachytherapy procedure permitted by 10 CFR 35.400.</p>

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.: 40-18000-01

Docket or Reference No.:
030-13778

Amendment No. 39

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Avera St. Luke's Hospital, 305 South State Street, Aberdeen, South Dakota, 57401.
11. The Radiation Safety Officer (RSO) for this license is Leslie H. Lenter, M.D.
12. Licensed material shall only be used by, or under the supervision of:
- A. Individuals permitted to work as an 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:

<u>Authorized Users</u>	<u>Material and Use</u>
Daniel R. Fritz, M.D.	35.100; 35.200; oral administration of sodium iodide I-131
Leslie H. Lenter, M.D.	35.100; 35.200; 35.300; 35.400, 35.1000 only Yttrium-90 SIR-Spheres®
Stephen R. Peters, M.D.	35.100; 35.200; 35.300
13. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
14. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

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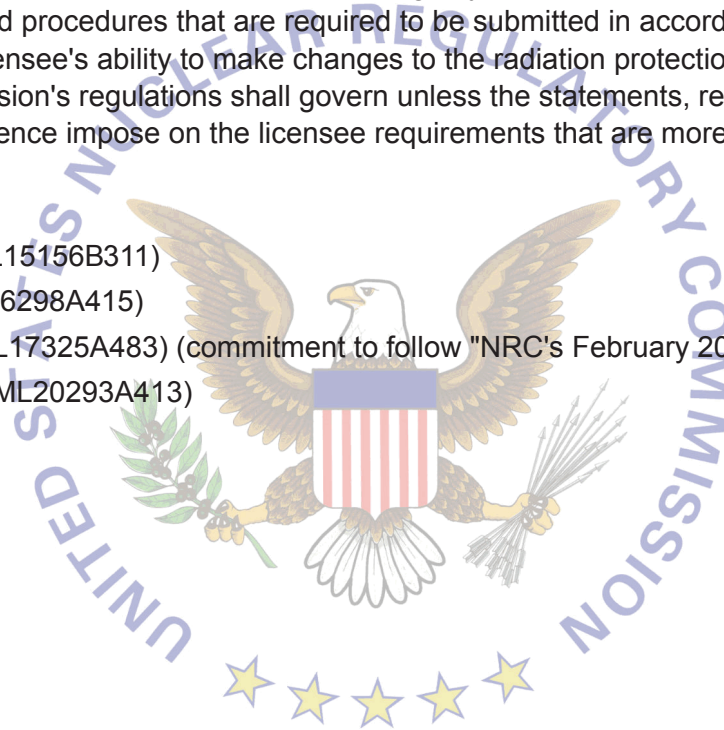
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15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license 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. 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 May 8, 2015 (ML15156B311)
- B. Letter dated October 3, 2016 (ML16298A415)
- C. Letter dated November 1, 2017(ML17325A483) (commitment to follow "NRC's February 2016 Microspheres Guidance" only)
- D. Letter dated September 21, 2020 (ML20293A413)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Latischa M. Hanson

Digitally signed by Latischa M.

Hanson

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By: _____

Latischa M. Hanson
Region IVDate: December 22, 2020