U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 38
Corrected Copy

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	In accordance with letters dated May 21, 2018, and June 13, 2018.	4. Expiration Date: November 30, 2025
1. Avera St. Luke's dba Avera St. Luke's Hospital		5. Docket No.: 030-13778 Reference No.:
2. 305 South State Street Aberdeen, SD 57401	3. License number: 40-18000-01 is amended in its entirety to read as follows:	

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 400 millicuries total	C. For any use permitted by 10 CFR 35.300.
D. Cesium-137 permitted by 10 CFR 35.400	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])	D. 940 millicuries total	D. For any manual brachytherapy procedure permitted by 10 CFR 35.400.

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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
E. Yttrium-90 permitted by 10 CFR 35.1000	E. Microspheres (manufacturer as listed in SSDR MA-1229-D-101-S, SIR-Spheres®,)	E. 189 mCi per vial and 1 curie total	E. SIR-Spheres® for permanent brachytherapy using delivery system as listed in SSDR MA-1229-D-101-S permitted by 10 CFR 35.1000.

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:

Authorized Users	Material and Use
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.

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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.

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 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 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)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: May 16, 2019

By: **/RA/**

Roberto J. Torres
Region IV