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 letter dated March 07, 2017.	4. Expiration Date: March 31, 2026
1. Saint Francis Medical Center		5. Docket No.: 030-02269 Reference No.:
2. 211 Saint Francis Dr. Cape Girardeau, MO 63703	3. License number: 24-00158-03 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. 1 curie total	C. For any use permitted by 10 CFR 35.300.
D. Any byproduct material permitted by 10 CFR 35.500	D. Sealed Sources (DuPont Pharma , Model NES 8412; North American Scientific, Model 3601)	D. 600 millicuries total	D. For diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered in accordance with 10 CFR 30.32(g).
E. Any byproduct material permitted by 10 CFR 31.11	E. Prepackaged Kits	E. 2 millicuries total	E. For use in in-vitro studies.

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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
F. Yttrium-90 permitted by 10 CFR 35.1000	F. Microspheres (Nordion (Canada), Inc., Model TheraSphere)	F. 540 millicuries per vial; 3 curies total	F. For medical use permitted by 10 CFR 35.1000 in a Nordion (Canada), Inc. TheraSphere yttrium-90 glass microsphere delivery system.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 211 Saint Francis Drive, Cape Girardeau, Missouri.

11. The Radiation Safety Officer (RSO) for this license is Mark L. Gates, M.D.

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
Mark Lewis Pfautsch, D.O.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)
Willeford J. Stoecker, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)
Craig W. Williams, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)
Tappan Roy, M.D.	10 CFR 35.300
Mark L. Gates, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.300,10 CFR 35.500

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Authorized User(M.D.,D.O.,etc.)	Material and Use
George A. Pjura, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.300,10 CFR 35.500
Theodore R. Swartz, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500
Jagannohan R. Alinani, M.D.	10 CFR 31.11,10 CFR 35.100,10 CFR 35.200,10 CFR 35.500
Rajinder M. Gulati, M.D.	10 CFR 31.11,10 CFR 35.100,10 CFR 35.200,10 CFR 35.300,10 CFR 35.500
Tom B. Brumitt, D.O.	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 35.1000 (limited to yttrium-90 as TheraSpheres)
James Borders, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500
Huan Nguyen, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500
Christopher Russell, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500
Andrew E. West, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500
Cedric Strange, M.D.	10 CFR 35.100,10 CFR 35.200,10 CFR 35.500
Paul H. Holcomb, M.D.	10 CFR 35.200
Derek L. Fimmen, M.D.	10 CFR 35.200
Shanaree M. Muzinich, M.D.	10 CFR 35.200
Jeffrey Wichman, M.D.	10 CFR 35.200
Evan Moser, D.O.	10 CFR 35.200
Michael Thomas, M.D.	10 CFR 35.100,10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)
Adam Ross Todd, M.D.	10 CFR 35.100,10 CFR 35.200; 10 CFR 35.1000 (limited to yttrium-90 as TheraSpheres)
William Michael Pelton, M.D.	10 CFR 35.200
Matthew Bokerman, M.D.	10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)
Richard Lyle Ogles, M.D.	10 CFR 35.100,10 CFR 35.200
Terrence Michael Chambers, M.D.	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)

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Authorized User(M.D.,D.O.,etc.)	Material and Use
Todd Michael Buersmeyer, 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 yttrium-90 as TheraSpheres)
Benjamin D. Goodman, M.D.	10 CFR 35.300 (limited to the oral administration of sodium iodide I-131 and the parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV)
James B. Winblad, M.D.	10 CFR 35.100,10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)
Jeffrey W. Boss, M.D.	10 CFR 35.100,10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)
Michael C. Muzinich, M.D.	10 CFR 35.100,10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)
Kyle W. Sanders, M.D.	10 CFR 35.100,10 CFR 35.200; 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)

13. 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 glass microspheres 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.

14. In accordance with letter dated March 7, 2017 (ML17066A355), the licensee may make changes to its radiation safety program, as it relates to the use of yttrium-90 microspheres as permitted by 10 CFR 35.1000, provided that:

    A. The revision is in compliance with the regulations;

    B. The revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Medical Uses Licensee toolkit;

    C. The revision has been reviewed and approved by the licensee's management;

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D. The affected individuals are instructed on the revised program before the change is implemented;

E. The licensee will retain a record of each change for 5 years; and

F. The record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

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. 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 September 8, 2015 (ML15253A911)
    B. Letter dated March 1, 2016 (ML16061A327)
    C. Letter dated March 7, 2017 (ML17068A355, limited to yttrium-90 as TheraSpheres)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: June 7, 2017

By: Sara A. Forster

Sara A. Forster
Region 3