U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 82

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 November 17, 2023,	4. Expiration Date: August 31, 2025
1. IOM Health System, LP d/b/a Lutheran Hospital of Indiana		
2. 7950 W. Jefferson Blvd. Fort Wayne, IN 46804	3. License No.: 13-01535-01 is amended in its entirety to read as follows:	5. Docket No.: 030-01594 Reference No.:

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.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.: 13-01535-01

Amendment No. 82

Docket or Reference No.: 030-01594

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
D. Iodine-125 permitted by 10 CFR 35.400	D. Sealed Sources (Bard, Model Model STM1251; Best Industries, Model Model 2301; Implant Sciences Corp., Model I-Plant Model 3500; IsoAid, LLC, Model Model IAI-125A; Mills Biopharmaceuticals, Inc., Model Model SL-125; SH-125; North American Scientific, Inc.,, Model Model MED 3631)	D. 1 curie total	D. For any manual brachytherapy procedure permitted by 10 CFR 35.400.
E. Palladium-103 permitted by 10 CFR 35.400	E. Sealed Sources (Best Medical International Inc., Model 2335; North American Scientific, Inc., Model MED 3633; Theragenics Corp., Model TheraSeed 200)	E. 1 curie total	E. For any manual brachytherapy procedure permitted by 10 CFR 35.400.
F. Cesium-131 permitted by 10 CFR 35.400	F. Sealed Sources (IsoRay Medical Inc., Model CS-1)	F. 1 curie total	F. For any manual brachytherapy procedure permitted by 10 CFR 35.400.
G. Any byproduct material permitted by 10 CFR 31.11	G. Prepackaged Kits	G. 1 millicurie total	G. For use in in-vitro studies.
H. Yttrium-90 permitted by 10 CFR 35.1000	H. Microspheres (Sirtex Medical Pty Ltd, Model SIR-Spheres)	H. Not to exceed 189 millicuries per vial and 2 curies total	H. For use in permanent manual brachytherapy using Sirtex Wilmington LLC Model SIR-Spheres Yttrium-90 microspheres and delivery system permitted by 10 CFR 35.1000.
I. Yttrium-90 permitted by 10 CFR 35.1000	I. Microspheres (BWXT Medical Ltd., Model TheraSpere)	I. Not to exceed 540 millicuries per vial and 3 curies total	I. For use in permanent manual brachytherapy using a BWXT Medical Ltd. Model TheraSphere Yttrium-90 microspheres and delivery system permitted by 10 CFR 35.1000.

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 13-01535-01	Docket or Reference No.: 030-01594
	Amendment No. 82	

CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at 7950 W. Jefferson Blvd., Fort Wayne, Indiana, 46804

11. The Radiation Safety Officer (RSO) for this license is Randall J. Phillips, 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 Users	Material and Use
Sanjiv G. Aggarwal, M.D.	10 CFR 35.100 and 35.200
James A. Arata, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Andrew V. Barger, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)
Jonathan Berger, M.D.	10 CFR 35.100 and 35.200
John L. Borman, M.D.	10 CFR 35.100, 35.200 and 35.300
Daniel Branam, M.D.	10 CFR 35.100, 35.200, and 35.300 (limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)
Nathan A. Cannon, M.D., Ph.D.	10 CFR 35.400
Andrew Ceranske, M.D.	10 CFR 35.100, 35.200 and 35.1000 (limited to yttrium-90 as TheraSpheres)
Nathan D. Comsia, M.D.	10 CFR 35.400
Joseph R. Decamp, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries)
Brett A. Hagedorn, M.D.	10 CFR 35.100, 35.200 and 35.300

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 13-01535-01	Docket or Reference No.: 030-01594
	Amendment No. 82	

Authorized Users	Material and Use
Eric V. Heatwole, M.D.	10 CFR 35.100 and 35.200
Joel Heitman, M.D.	10 CFR 35.100 and 35.200
Saad M. Ibrahim, M.D.	10 CFR 35.1000 (limited to yttrium-90 as SIR-Spheres and TheraSpheres)
David B. Janizek, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Christopher M. Kowalski, M.D.	10 CFR 35.100 and 35.200
Brady Laughlin, D.O.	10 CFR 35.300 and 10 CFR 35.1000 (limited to the yttrium-90 as TheraSpheres)
Jonathan M. Lee, M.D.	10 CFR 35.300 (limited to the oral administration of sodium iodide I-131) and 35.1000 (limited to yttrium-90 as TheraSpheres)
John C. Lucunza, M.D.	10 CFR 35.100 and 35.200
Rao V.P. Mantravadi, M.D.	10 CFR 35.300 and 35.400
Scott E. Mattson, D.O.	10 CFR 35.100 and 35.200
Indu Rekha Meesa, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131)
Mark A. Meier, M.D.	10 CFR 35.200
Michael E. Parker, M.D.	10 CFR 35.100, 35.200 and 35.300
John Pasalich, M.D.	10 CFR 35.100, 35.200 and 35.300
Dakshesh S. Patel, M.D.	10 CFR 35.100 and 35.200
Randall J. Phillips, M.D.	10 CFR 35.100, 35.200, 35.300, 35.1000 (limited to yttrium-90 as SIR-Spheres) and 31.11
Venkata Rama Prasad Nalamolu, M.D.	10 CFR 35.200
Krishnan Ramani, M.D.	10 CFR 35.200
Mark C. Ranck, M.D.	10 CFR 35.400
John Rock, M.D.	10 CFR 35.100, 35.200 and 31.11
Wesley A. Russell, M.D.	10 CFR 35.400
Vivek Sharma, M.D.	10 CFR 35.100 and 35.200
Eugene Shih, M.D.	10 CFR 35.100 and 35.200

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 13-01535-01	Docket or Reference No.: 030-01594
	Amendment No. 82	

Authorized Users	Material and Use
Richard W. Sibley, M.D.	10 CFR 35.100, 35.200 and 35.300
Rik Stephens, M.D.	10 CFR 35.100, 35.200, 35.300 and 31.11
Andre Byard Stovall, M.D.	10 CFR 35.100, 35.200, 35.300, and 35.1000 (limited to yttrium-90 as SIR-Spheres)
Pamela Lee Strange, M.D.	10 CFR 35.100, 35.200 and 35.300
Marc Thomas, M.D.	10 CFR 35.100, 35.200 and 35.300
Benjamin A. Tourkow, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131)
Edward K. Yi, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide I-131)

MATERIALS LICENSE SUPPLEMENTARY SHEET	License No.: 13-01535-01	Docket or Reference No.: 030-01594
	Amendment No. 82	

13. 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 12, 2015 (ML15146A271)
B. Letter dated May 12, 2015 (ML15146A271)
C. Letter dated June 18, 2015 (ML15175A296)
D. Letter dated February 17, 2017 (ML17201J344)
E. Letter dated September 3, 2019 (ML19248C703)
F. Letter dated April 13, 2020 (ML20107J534)
G. Letter dated July 28, 2020 (ML20217L341)
H. Letter dated November 17, 2023 (ML23333A471)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: January 19, 2024

By: Digitally signed by Jason M. Kelly
Date: 2024.01.19 14:16:01 -06'00'
Adobe Acrobat version: 2023.008.20421

Jason M. Kelly, MPH, CPH
Health Physicist
Region III