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June 1, 2020

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Via Fax: 630-515-1078

Dear Reader:

Re NRC License Number 24-00128-03

Part 1

We request an amendment to authorize Patrick M. Keating, M.D. for 10 CFR 35.1000 (limited to the use of yttrium-90 as TheraSpheres). Dr. Keating is currently authorized on our license for 10 CFR 35.100 35.200, and 35.300 (limited to the oral administration of sodium iodide I-131 in quantities of 33 millicuries or less). He is authorized for use of yttrium-90 as TheraSpheres on NRC License 24-00158-03, Saint Francis Medical Center, Cape Girardeau, Missouri, a copy of which is attached hereto.

Part 2

In accordance with "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" Revision 10.1, Section 5.5 "Notification", we request authorization to notify the NRC in the future that we have permitted an AU to work at our facility as a user of yttrium TheraSpheres without requesting an additional license amendment. We commit to compliance with conditions 1-5 of section 5.5.

If you have any questions regarding this application, please feel free to call me at 573-519-4710 (office) or 573-270-7492 (mobile).

Sincerely,

A handwritten signature in black ink that reads "Sam S. Hancock PhD".

Sam S. Hancock, PhD
Radiation Safety Officer

Enclosures:

cc: Mariellena Sudak, VP, COO
Mark Gates, MD, RSC Chairman

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

JAN 27 2020

Mark L. Gates, M.D.
Radiation Safety Officer
Saint Francis Medical Center
211 Saint Francis Dr.
Cape Girardeau, MO 63703

Dear Dr. Gates:

Enclosed is Amendment No. 78 to your U.S. Nuclear Regulatory Commission (NRC) Material License No. 24-00158-03 for Saint Francis Medical Center in accordance with your request dated November 12, 2019. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the NRC Region III office at (630) 829-9887 so that we may provide appropriate corrections and answers.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. The NRC may issue a notice of violation, imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

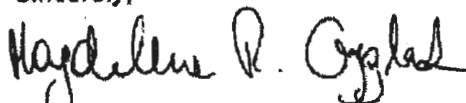
The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

M. Gates

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In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 24-00158-03
Docket No. 030-02269

Enclosure: Amendment No. 78

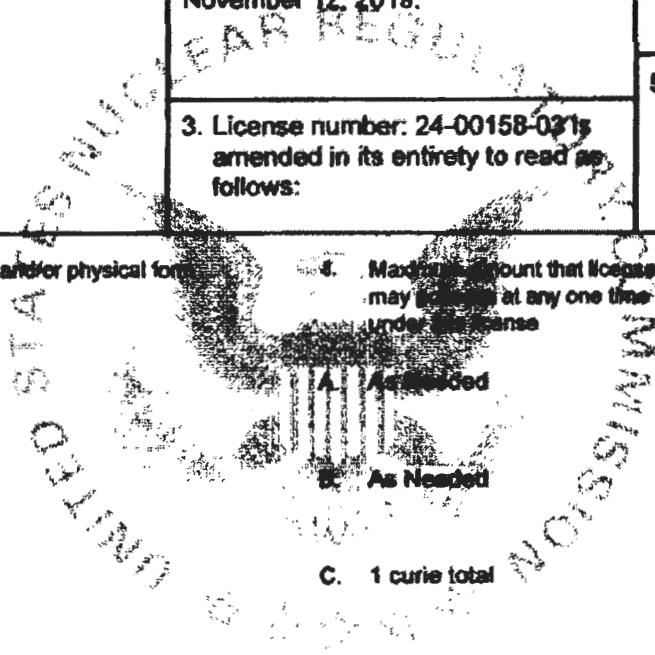
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Samuel Hancock SE Cancer Center

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 1. Saint Francis Medical Center 2. 211 Saint Francis Dr. Cape Girardeau, MO 63703		In accordance with letter dated November 12, 2019.	4. Expiration Date: March 31, 2028
		3. License number: 24-00158-021; amended in its entirety to read as follows:	5. Docket No.: 030-02269 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.
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.



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
24-00158-03

Docket or Reference Number
030-02269

Amendment No. 78

- | 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 use in permanent manual brachytherapy using Nordion (Canada), Inc. TheraSphere yttrium-90 microspheres delivery system as permitted by 10 CFR 35.1000. |
| G. Yttrium-90 permitted by 10 CFR 35.1000 | G. Microspheres (Sirtex, Model SIR-Spheres delivery system) | G. 189 millicuries per vial; 1 curie total | G. For use in permanent manual brachytherapy using Sirtex Model SIR-Spheres yttrium-90 microspheres delivery system as permitted by 10 CFR 35.1000. |

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 211 Saint Francis Dr., Cape Girardeau, Missouri, 63703.
11. The Radiation Safety Officer (RSO) for this license is Mark L. Gates, M.D.

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Samuel Hancock SE Cancer Center

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 24-00158-03
Amendment No. 78

Docket or Reference Number 030-02269

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:

<u>Authorized User(M.D.,D.O.,etc.)</u>	<u>Material and Use</u>
Marc A. Apostol, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)
Matthew Bokerman, M.D.	10 CFR 35.100, 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)
James Borders, M.D.	10 CFR 35.100, 10 CFR 35.500
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)
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)
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 and as SIR-Spheres)
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)
Randall Clark, D.O.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)
Derek L. Fimmen, M.D.	10 CFR 35.200
Mark L. Gates, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.500
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)
Patrick M. Keating, 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)

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
24-00158-03

Docket or Reference Number
030-02269

Amendment No. 78

Authorized User(M.D.,D.O.,etc.)

Material and Use

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);

Shanaree M. Muzinich, M.D.

10 CFR 35.200

Huan Nguyen, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.500

Richard Lyle Ogles, M.D.

10 CFR 35.100,10 CFR 35.200

Sagar Patel, M.D.

10 CFR 35.300

Mark Lewis Pfautsch, 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 35.500

George A. Pjura, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.300,10 CFR 35.500

Tappan Roy, M.D.

10 CFR 35.100

Christopher Russell, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.500

Ryan Siebert, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.300 (limited to the oral administration of sodium iodide I-131)

Cedric Strange, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.500

Theodore R. Swartz, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.500

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)

Andrew E. West, M.D.

10 CFR 35.100,10 CFR 35.200,10 CFR 35.500

Jeffrey Wichman, M.D.

10 CFR 35.200

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 (ML17068A355), 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.

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Samuel Hancock SE Cancer Center

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Samuel Hancock SE Cancer Center

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

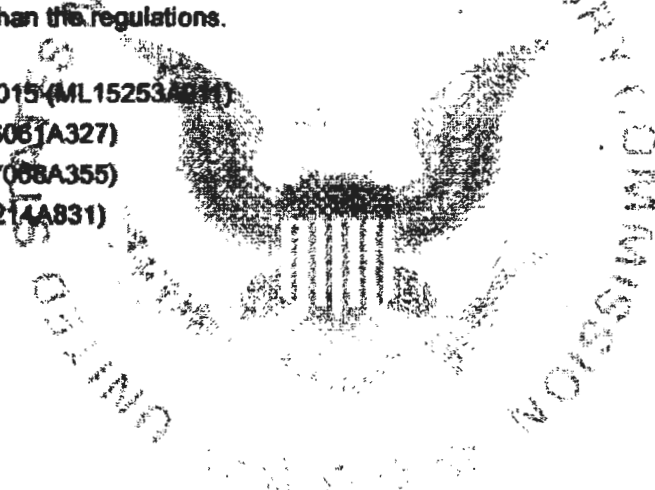
License Number
24-00158-03

Docket or Reference Number
030-02269

Amendment No. 78

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 (ML15253A311)
- B. Letter dated March 1, 2016 (ML16061A327)
- C. Letter dated March 7, 2017 (ML17088A355)
- D. Letter dated July 27, 2017 (ML17214A831)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: JAN 27 2020

By: Magdalena R. Gryglak
 Magdalena R. Gryglak
 Region 3