NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 23
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 an NRC review on December 14, 2017	4. Expiration Date: June 30, 2025
1. Nemours - Alfred I. duPont Hospital for Children		5. Docket No.: 030-19939 Reference No.:
2. 1600 Rockland Road Wilmington, DE 19803	3. License number: 07-16199-02 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. Iodine-131 permitted by 10 CFR 35.300	C. Any	C. 1 curie total	C. For any use permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.
D. Technetium-99m	D. Any	D. 100 millicuries total	D. For verification of shielding at the licensee's facility.
E. Fluorine-18	E. Any	E. 1 curie total	E. For research and development as defined in 10 CFR 30.4.

MATERIALS LICENSE SUPPLEMENTARY SHEET

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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	F. 540 mCi per source and 1 curie total	F. For use in permanent manual brachytherapy using MDS Nordion, Inc. Model TheraSphere Yttrium-90 microspheres and delivery system permitted by 10 CFR 35.1000.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 1600 Rockland Road, Wilmington, Delaware.

11. The Radiation Safety Officer (RSO) for this license is Kelly A. Sciole, CNMT.

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. Physicians permitted to work as authorized users for Yttrium-90 TheraSpheres in accordance with the notification commitments related to documentation of three proctored cases as required in the letter dated August 31, 2017.

C. 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 Finklestein, D. O.	10 CFR 35.100,10 CFR 35.200
Kerry Allison Bron, M. D.	10 CFR 35.100,10 CFR 35.200
Harry Chugani, M.D.	10 CFR 35.100,10 CFR 35.200,F18
Thang Ngo, M.D.	10 CFR 35.100, 10 CFR 35.200, Oral administration of sodium iodide I-131

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Authorized User(M.D.,D.O.,etc.)	Material and Use
David Dinan, M.D.	10 CFR 35.100,10 CFR 35.200
Steven Blummer, M.D.	10 CFR 35.100,10 CFR 35.200
Tejal Mody, M.D.	10 CFR 35.100, 10 CFR 35.200, Oral administration of sodium iodide I-131
Allison Aguado, M.D.	Yttrium-90 TheraSpheres

D. The following individuals are authorized users for nonmedical uses as indicated:

Authorized Users	Material and Use
Marc A. Felice	Technetium-99m for shielding verification
Harry Chugani, M.D.	Fluorine-18 for research defined by 10 CFR 30.4

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. 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 December 31, 2014 [ML15016A086]

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continued

B. Letter dated April 27, 2015 [ML15149A367]
C. Letter received June 23, 2015 [ML15201A572]
D. Letter dated November 2, 2016 [ML16326A053]
E. Letter dated December 14, 2016 [ML17010A141]
F. Letter dated December 23, 2016 [ML17004A255]
G. Letter dated January 6, 2017 [ML17013A574]
H. Letter dated February 5, 2017 [ML17067A461]
I. Letter dated February 28, 2017 [ML17076A194]
J. Letter dated August 30, 2017 [ML17243A403]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: December 14, 2017

By: _____
Penny Lanzisera
Region 1