

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5, Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida, Department of Health now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Name: THE NEMOURS FOUNDATION d/b/a Nemours Children's Health, Florida</p>	<p>3. License Number: 4332-1 is hereby amended in its entirety with reference to correspondence received February 4, 2022.</p>
<p>2. Address: 6535 Nemours Parkway Orlando, FL 32827</p>	<p>4. Expiration Date: 1/31/2026 5. Category: 5B</p>

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
A. Any radioactive material described in section 64E-5.626(1) and (2), F.A.C.	A. Any radiopharmaceutical for diagnostic use involving measurements of uptake, dilution or excretion as described in section 64E-5.626(1) and (2), F.A.C.	A. 500 millicuries
B. Any radioactive material described in section 64E-5.627(1) and (2), F.A.C.	B. Any radiopharmaceutical for diagnostic use involving imaging and localization as described in section 64E-5.627(1) and (2), F.A.C.	B. 2 curies
C. Any radioactive material described in section 64E-5.630(1), F.A.C.	C. Any radiopharmaceutical for therapeutic use as described in section 64E-5.630(1), F.A.C.	C. 5 curies

9. Authorized Use
A. Any medical use described in section 64E-5.626(1) and (2), F.A.C.
B. Any medical use described in section 64E-5.627(1) and (2), F.A.C.

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9. Authorized Use Continued:

C. Any medical use described in section 64E-5.630(1), F.A.C.

CONDITIONS

10. The authorized place of use is the licensee's facility located at the address in Item 2.
11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to \$1,000.00 per violation per day, pursuant to section 404.162, Florida Statutes.
12. A. Radiopharmaceuticals which are prepared from generators and/or reagent kits shall be either a FDA approved NDA, ANDA, IND, or prescribed by an Authorized User. The following individuals or persons under their supervision are authorized for the materials and uses as indicated:

Authorized Material and Uses as Described in Items 6, 7, 8 and 9	Names
64E-5.626(1), (2), 64E-5.627(1), (2) and 64E-5.630(1)	Pankaj Watal, MD Stephen L.E. Bresson, MD
64E-5.626(1), (2), 64E-5.627(1), (2) and 64E-5.630(2) (3)	Tejal Mody, MD Fabiola C. Weber-Guzman, MD
64E-5.626(1), (2), 64E-5.627(1), (2) and 64E-5.630(3)	Wael Abdalla, MD
64E-5.626(1), (2) and 64E-5.627(1), (2)	Zahir U. Sawar, MD Robert De Florio, MD Elizabeth P. McGraw, MD Candace D. Scace, MD Jennifer N. Kucera, MD
64E-5.626(1) and 64E-5.627(1)	David Dinan, MD Kerry Allison Bron, MD Craig M. Johnson, DO Kathleen E. Schenker, MD Laura Lee Hayes, MD Rahul Nikam, MD

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12. A. Continued

Authorized Material and Uses as Described in Items 6, 7, 8 and 9	Names
64E-5.626(1) and 64E-5.627(1)	William R. Bireley, MD Howard K. Christianson, MD Raphael Yoo, MD Lena N. Naffaa, MD

B. The radiation safety officer is Stefani Krall, RT (R)(N), CNMT.

C. Radiologic technologists who use and administer radioactive materials or perform brachytherapy or teletherapy procedures under the general supervision of an authorized user shall hold a valid certificate as required by Chapter 468, F.S.

13. Radioactive material transported on public thoroughfares shall be packaged, prepared for shipment, and transported in accordance with Title 49, Code of Federal Regulations and Chapter 64E-5, F.A.C.

14. Sealed sources containing licensed material shall not be opened.

15. The licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:

A. The dose rate is less than 5 millirem (50 microsieverts) per hour at a distance of 1 meter;

B. The amount of radioactive material in the patient is less than 30 millicuries; or

C. The patient is released under the terms of 64E-5.622(4), F.A.C. and Condition 17.

16. Any dose of iodine 131 shall be received in capsule form only.

17. A. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, 8 and 9 of this license in accordance with statements, representations and procedures contained in the licensee's application and attestation dated January 6, 2021, signed by Chris Alsip, MHA, RT(R)(CT), Deputy COO, and correspondence received:

July 13, 2021 (Appendix A), signed by Chris Alsip, MHA, RT (R)(CT), Deputy COO.

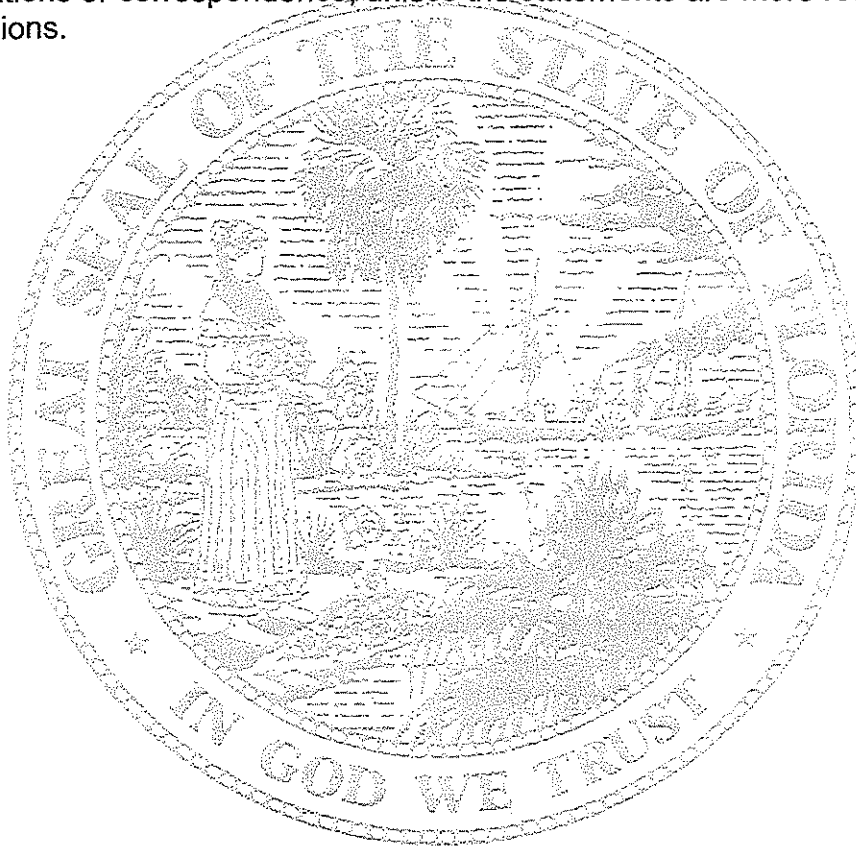
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17. B. The licensee shall comply with all applicable requirements of Chapter 64E-5, Florida Administrative Code, and these regulations shall supersede the licensee's statements in applications or correspondence, unless the statements are more restrictive than the regulations.



For the Bureau of Radiation Control:

Issuance Date: MAR 24 2022

Megan Thorpe

Megan Thorpe
Environmental Specialist III
4052 Bald Cypress Way – Bin C21
Tallahassee, FL 32399-1741
850-245-4545

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. Such proceedings are governed by Rule 28-106, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this order. The address of the Agency Clerk is: Agency Clerk, 4052 Bald Cypress Way, BIN # A02, Tallahassee, Florida 32399-1703. The Agency Clerk's facsimile number is 850-410-1448. A copy of the petition should also be sent to: Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, BIN # C21, Tallahassee, FL 32399-1741. The Bureau Chief's facsimile number is 850-487-0435. Mediation is not available as an alternative remedy. Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a "final order." Should this order become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

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