



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

November 3, 2022

Mark Mumford
EVP Chief Executive Delaware Operations
Nemours Children's Hospital, Delaware
1600 Rockland Road
Wilmington, Delaware 19803

SUBJECT: NEMOURS CHILDREN'S HOSPITAL, DELAWARE, LICENSE AMENDMENT,
MAIL CONTROL NO. 632518

Dear Mr. Mumford:

This refers to your license amendment request dated August 3, 2022. Please find enclosed Amendment No. 27 authorizing Wael Abdalla, M.D., Jennifer Kucera, M.D., and Rahul Nikam, M.D. as Authorized Users and removing David Dinan, M.D., and Tejal Mody, M.D. as requested. Please note that the following changes were also made to your license:

1. The authorized research use of Fluorine-18 as listed on your license was changed from research and development under 10 CFR 30.4 to human research under the provisions of 10 CFR 35.6 since you indicated all research conducted under this license is clinical and not benchtop or animal research.
2. The listings for microspheres were updated to reflect the current description in the Sealed Source and Device Registry.
3. Condition 12B was removed as it is no longer necessary. Allison Aguado, M.D. completed the required three proctored cases by the TheraSphere vendor on December 18, 2017, October 29, 2018, and February 11, 2021.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at (610) 337-5076 or via electronic mail at robin.elliott@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the 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(s) against you. This could include issuance of a Notice of Violation, or Imposition of a Civil Penalty, or an Order Suspending, Modifying or Revoking Your License as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

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/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.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

Robin L. Elliott, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 07-16199-02
Docket No. 030-19939
Mail Control No. 632518

Enclosure:
Amendment No. 27

cc: Kelly Sciole, Radiation Safety Officer

NEMOURS CHILDREN'S HOSPITAL, DELAWARE, LICENSE AMENDMENT, MAIL CONTROL
NO. 632518 DATED November 3, 2022

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SUNSI Review Complete: RElliott

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