



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BLVD.  
KING OF PRUSSIA, PA 19406-2713

March 21, 2017

Kelly Sciole, CNMT  
Nemours – Alfred I duPont Hospital for Children  
1600 Rockland Road  
Wilmington, Delaware 19803

SUBJECT: NEMOURS – ALFRED I DUPONT HOSPITAL FOR CHILDREN, LICENSE  
AMENDMENT, MAIL CONTROL NO. 592696

Dear Mrs. Sciole:

This refers to your license amendment request dated December 14, 2016. Please find enclosed Amendment No. 21 authorizing the use of Fluorine 18 for collection of research data to support an IND request to the FDA to produce a radiopharmaceutical. We understand that upon approval from FDA, the pharmaceutical will be administered to patients.

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) 337-5143 or via electronic mail at [Farrah.Gaskins@nrc.gov](mailto:Farrah.Gaskins@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](http://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 "Rules of Practice," 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,

*/ RA /*

Farrah C. Gaskins, Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety  
Region I

License No. 07-16199-02  
Docket No. 030-19939  
Mail Control No. 592696

Enclosure:  
Amendment No. 21

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 "Rules of Practice," 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,

**/ RA /**

Farrah C. Gaskins, Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety  
Region I

License No. 07-16199-02  
Docket No. 030-19939  
Mail Control No. 592696

Enclosure:  
Amendment No. 21

DOCUMENT NAME: G:\WBL Documents\WBL License Cover Letter\L06-16199-02.592696.docx

**ML17086A411**

**SUNSI Review Complete: [FGaskins]**

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	RI:DNMS	N					
NAME	FGaskins/FG						
DATE	03/21/2017						

OFFICIAL RECORD COPY