

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Nemours – Alfred I. duPont Hospital for Children 1600 Rockland Road Wilmington, DE 19803  REPORT NUMBER(S) 2019-001		2. NRC/REGIONAL OFFICE  U.S. Nuclear Regulatory Commission Region I, 2100 Renaissance Blvd, Suite 100 King of Prussia, Pennsylvania 19406-2713	
3. DOCKET NUMBER(S) 030-19939	4. LICENSE NUMBER(S) 07-16199-02	5. DATE(S) OF INSPECTION June 3, 2019; exit on October 29, 2019	

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☐ 1. Based on the inspection findings, no violations were identified.
- ☒ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s) and corrective action(s):

- ☒ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with the NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11. (Violations and Corrective Actions)

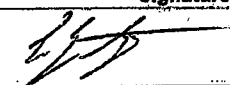
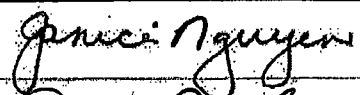
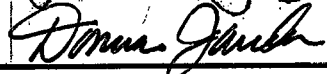
1. 10 CFR 35.24(f) requires, in part, that the Radiation Safety Committee (RSC) must include an authorized user of each type of use permitted by the license.

Contrary to the above, from June 5, 2018 to June 3, 2019, Nemours' RSC did not include an authorized user of each type of use permitted by the license. Specifically, the RSC did not include an authorized user of Yttrium-90 microspheres permitted by 10 CFR 35.1000.

This is Severity Level IV violation (Enforcement Policy Section 6.3). Corrective actions include appointing a Yttrium-90 microspheres authorized user to the RSC.

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE	ERIC SCHANTZENBACH		10/29/19
NRC INSPECTOR	Janice Nguyen		10-29-19
BRANCH CHIEF	Donna Janda		10/30/19

\*NRC FORM 591M PART 1 (07-2012) (RI Rev. 09/12/2013) G:\WBL Documents\WBL Inspection Records\R07-16199-02.2019-001.591M-Part1.doc

SUNSI Review Completed By: / RA / Janice Nguyen



Public



Non-Sensitive

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Wilmington, DE 19803

REPORT NUMBER(S)

2019-001

**2. NRC/REGIONAL OFFICE:**

U.S. Nuclear Regulatory Commission  
Region I, 2100 Renaissance Blvd, Suite 100  
King of Prussia, Pennsylvania 19406-2713

**3. DOCKET NUMBER(S)**

030-19939

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**5. DATE(S) OF INSPECTION**

June 3, 2019; exit on October 29, 2019

(Continued)

2. 10 CFR 35.60(a) requires that for direct measurements performed in accordance with 10 CFR 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject. 10 CFR 35.60(b) requires that the licensee calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, as of June 3, 2019, the licensee did not calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, Nemours did not perform geometrical variation testing on the two dose calibrators in the PET Chemistry Department.

This is a Severity Level IV violation (Enforcement Policy Section 6.3). Corrective actions include performing geometrical variation testing on the two dose calibrators in the PET Chemistry Department, and retraining staff on dose calibrator testing requirements.

3. 10 CFR 35.67(b)(2) requires, in part, that a licensee in possession of a sealed source shall test the source for leakage at intervals not to exceed 6 months. 10 CFR 35.67(g) requires, in part, that a licensee in possession of sealed sources shall conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, as of June 3, 2019, Nemours did not test the sealed sources in its possession for leakage at intervals not to exceed 6 months and did not conduct a semi-annual physical inventory of all such sources in its possession. Specifically, the three dose calibrator vial sources and one rod source in the PET Chemistry Department had not been inventoried or leak tested.

This is a Severity Level IV violation (Enforcement Policy Section 6.3). Corrective actions include performing a sealed source inventory and leak test on the sealed sources in the PET Chemistry Department, and retraining staff on sealed source requirements.

4. 10 CFR Part 71.5(a) requires, in part, that any licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, comply with the applicable requirements of the Department of Transportation (DOT) regulations in 49 CFR Parts 171 through 180, appropriate to the mode of transport.

49 CFR 172.400(a) requires, in part, that each person who offers for transportation or transports a hazardous material shall label the package with labels and markings specified for the material in the 172.101 table and in this subpart (i.e., Radioactive White I or Yellow II).

Contrary to the above, as of June 3, 2019, Nemours did not label the package with labels and markings specified for the material in the 172.101 table and in this subpart (i.e., Radioactive White I or Yellow II). Specifically, packages containing between 20 to 500 uCi of Fluorine-18 were transported from the PET Chemistry Department to the Nemours Life Science Center without being labeled as Radioactive White I or Yellow II as required nor were they marked with the proper shipping name. Furthermore, the closure device of the packaging was not installed and secured before each shipment. Additionally, the shipping paper accompanying the package did not contain the required shipper's certification that the package had been shipped in accordance with the DOT regulations.

This is a Severity Level IV violation (Enforcement Policy Section 6.8). Corrective actions include developing a procedure for the labeling and marking of packages containing radioactive material, providing package closure devices (i.e., zip ties), revising the shipping paper to include the correct language, and retraining staff on the transportation requirements for radioactive material.