



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

February 15, 2013

Docket No. 03001242
EA-13-013

License No. 06-00649-03

Garrett Havican
Vice President, Operations
Middlesex Hospital
28 Crescent Street
Middletown, CT 06457

SUBJECT: NRC INSPECTION REPORT NO. 03001242/2012001, EXERCISE OF ENFORCEMENT DISCRETION; MIDDLESEX HOSPITAL, MIDDLETOWN, CONNECTICUT SITE

Dear Mr. Havican:

On October 24, 2012, Janice Nguyen of this office conducted a safety inspection at the above address and at 530, 534, and 536 Saybrook Road, Middletown, Connecticut, of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and an examination of records. Additional information provided in the amendment request dated November 14, 2012, was also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection on January 17, 2013.

Based on the results of this inspection, the NRC has determined that one violation of NRC requirements occurred. This violation involved 10 CFR 30.3(c)(2) which states, in part, that licensees who possess and use accelerator-produced radioactive material for which a license amendment is required to authorize the activities in 10 CFR 30.3(a), may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided the person submits an amendment application within 6 months from the waiver expiration date of August 7, 2009. Contrary to the above, Middlesex Hospital (Middlesex) used accelerator-produced radioactive material (e.g., PET radioisotopes) at its 534 Saybrook Road location for which a license amendment was required to authorize activities in 10 CFR 30.3(a) and did not submit an amendment application within 6 months from the waiver expiration date of August 7, 2009. Specifically, Middlesex submitted an amendment application to add their 534 Saybrook Road PET/CT department and the use of fluorine-18 on November 16, 2012, which was not within 6 months from the waiver expiration date. Prior to the October 24, 2012, inspection, you and your staff indicated that Middlesex Hospital was unaware that the NRC had jurisdiction and believed that the materials were still authorized by the State of Connecticut.

This violation would normally be categorized at Severity Level IV; however, in accordance with NRC Enforcement Guidance Memorandum (EGM) 09-004, dated May 13, 2009, the NRC will exercise discretion and not issue a violation. The NRC's decision is based on the criteria listed in EGM 09-004. Specifically, 1) this was the first occurrence involving Middlesex Hospital after August 7, 2009, the effective date of the requirement; 2) the failure did not result in an actual safety, health, or security consequence; 3) the failure was not willful; and 4) Middlesex Hospital was unaware of the requirement. Additionally, you agreed to submit a request for a license amendment to add the PET facility and use of fluorine-18 to your license within 30 days. The request for the license amendment was received in the Region I office on November 16, 2012.

On January 17, 2013, Ms. Nguyen informed you of this conclusion by telephone and stated that a letter documenting the conclusion would be issued. No further action or response is required on your part. In the future, should Middlesex Hospital want authorization to possess byproduct material that is not listed on your license, Middlesex Hospital must submit a license amendment request to the NRC and receive authorization prior to using the material.

Please contact Janice Nguyen at 610-337-5006 if you have any questions regarding this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC document system (ADAMS), accessible from the NRC website at <https://www.nrc.gov/reading-rm/adams.html>. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement is 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/regulatory/enforcement/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.

G. Havican

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Thank you for your cooperation.

Sincerely,

/RA/

Raymond K. Lorson, Director
Division of Nuclear Materials Safety

cc:
Joan Merton, Radiation Safety Officer
State of Connecticut

G. Havican

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Thank you for your cooperation.

Sincerely,

/RA/

Raymond K. Lorson, Director
Division of Nuclear Materials Safety

cc:

Joan Merton, Radiation Safety Officer
State of Connecticut

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