



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

February 27, 2017

EA-17-004

Docket No. 03001244

License No. 06-00819-03

Arthur P. Lemay, M.S., R.Ph.
Executive Director
Smilow Cancer Hospital Network
Yale-New Haven Hospital
Radiological Physics
20 York Street – WWW 229
New Haven, CT 06510

SUBJECT: NRC INSPECTION REPORT NO. 03001244/2016002, YALE-NEW HAVEN HOSPITAL, NEW HAVEN, CONNECTICUT SITE AND NOTICE OF VIOLATION

Dear Mr. Lemay:

On May 25-26, 2016, Penny Lanzisera and Farrah Gaskins of this office conducted a safety inspection at your facility, with continued in-office review through February 14, 2017. 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 inspectors, interviews with personnel, and a selective examination of representative records. The inspectors also reviewed information provided in your correspondence dated January 24, 2017; and the secure email dated February 14, 2017. The findings of the inspection were discussed during telephone conversations on January 17 and February 2, 2017, with your Radiation Safety Officer, Mr. Michael Bohan, at the conclusion of the inspection.

Based on the results of this inspection, the NRC determined that five Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the Notice of Violation (Notice), provided as Enclosure 1 to this letter, because they were identified by NRC. Enclosure 2 provides a determination of severity level and a description of the corrective actions taken by Yale-New Haven Hospital to address each violation.

The NRC has concluded that the reasons for three of the violations and the corrective actions taken and planned to correct each of these violations and prevent recurrence are already adequately addressed in our records. Therefore, you are not required to respond to this letter for those violations unless the description of your corrective actions in Enclosure 2 does not accurately reflect your actions or your position. For two of the violations, you are required to respond to this letter and should follow the instructions specified in the enclosed Notice when

Enclosures contain Sensitive Unclassified Non-Safeguards Information. Upon separation, this cover letter is decontrolled.

A. Lemay

2

preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. If Security-Related Information is necessary to provide an acceptable response please mark the top of each page of your response, "Security-Related Information – Withhold Under 10 CFR 2.390." To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information. In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for your response.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room located at NRC Headquarters in Rockville, MD, and from the NRC's document system, the Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. However, the material enclosed herewith contains Security-Related Information in accordance with 10 CFR 2.390(d)(1) and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in the enclosures will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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.

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).

A. Lemay

3

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosures:

1. Notice of Violation
2. Determination of Severity Level
and Description of Corrective Actions

cc with Enclosures: Michael J. Bohan,
Radiation Safety Officer

cc w/o Enclosures: State of Connecticut

Official Use Only – Security-Related Information

A. Lemay

3

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosures:

- 1. Notice of Violation
- 2. Determination of Severity Level
and Description of Corrective Actions

cc with Enclosures: Michael J. Bohan,
Radiation Safety Officer

cc w/o Enclosures: State of Connecticut

DISTRIBUTION:

ADAMS (PARS)

JPeralta, OE

NHasan, OE

SRodriguez, OE

LSreenivas, OE

MBurgess, NMSS

RSun, NMSS

SHoliday, NMSS

JTrapp, RI

JNick, RI

JDwyer, RI

PLanzisera, RI

FGaskins, RI

BKlukan, RI

R1Enforcement

DBearde, RI

SVillar, RI

Region I OE Files (with concurrences)

DOCUMENT NAME: G:\WBL Documents\WBL Inspection Letter\L06-00819-03.2016002.Public.docx

SUNSI Review Complete: PLanzisera

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	DNMS/RI	N	DNMS/RI	N	OE/RI	DNMS/RI
NAME	PLanzisera/PL via email		FGaskins/fcg		Bickett/mmm for	Dwyer/jpd
DATE	02/22/17		02/22/17		02/22/17	02/24/17
OFFICE	DNMS/RI					
NAME	JTrapp/jmt					
DATE	02/27/17					

OFFICIAL RECORD COPY