



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

September 14, 2018

Arthur P. Lemay, M.S., R.Ph.
Executive Director
Smilow Cancer Hospital Network
Yale-New Haven Hospital
Radiological Physics
20 York Street, WWW 204
New Haven, CT 06504

SUBJECT: YALE-NEW HAVEN HOSPITAL - NRC INSPECTION NO. 03001244/2018001
AND NOTICE OF VIOLATION

Dear Mr. Lemay:

This letter refers to the inspection conducted on May 14-17, 2018 with continued in office review and exit meeting on August 21, 2018, at your New Haven and Norwich, Connecticut facilities. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that three safety Severity Level IV (SL IV) violations and seven SL IV security-related violations of NRC requirements occurred. All of the violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notices of Violation (Notice) because the violations were identified by the NRC.

The violations associated with the security inspection are cited in the enclosed, non-public Notice of Violation (Notice, Enclosure 1). The basis for the significance determination, discussion of why the violations are of concern to the NRC, and a description of the corrective actions taken by Yale-New Haven Hospital (YNHH) are provided in the non-public Enclosure 2 (Final Determination of Significance and Description of Corrective Action). The NRC has characterized the security violations as a single SL IV problem in recognition that they share a common root cause of the failure by YNHH to provide adequate oversight of its nuclear security program, as more fully described in Enclosure 2.

The violations associated with the safety inspection are cited in the enclosed Notice of Violation (Notice, Enclosure 3). The violations included YNHH's failure to: (1) conduct radiation surveys in use areas at the end of each day of use; (2) provide annual emergency instruction and drills to all users of the gamma knife; (3) conduct an annual review of the radiation safety program content and implementation. The NRC has concluded that the root cause of all three violations

Enclosures 1 and 2 contain Sensitive Unclassified Non-Safeguards Information Upon separation, this cover letter is DECONTROLLED.

A. Lemay

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was YNHH's failure to provide adequate oversight of its radiation protection program and this demonstrated a programmatic weakness. Therefore, these violations have been categorized collectively as a single SL IV problem to emphasize the importance of providing suitable resources and focus on radiation safety program implementation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notices when 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. The NRC review of your responses to the Notices will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and the publically available enclosure (Notice, Enclosure 3) 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 as described above. Therefore, the material in enclosures 1 and 2 will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

If you have any questions regarding this matter, please contact Robin Elliott of my staff at (610) 337-5076 or via electronic mail at robin.elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 030-01244
License No. 06-00819-03

Enclosures:

1. Notice of Violation – Security (Non-Public)
2. Determination of Severity Level
and Description of Corrective Actions (Non-Public)
3. Notice of Violation – Safety (Public)

cc w/Encls: Michael J. Bohan, Radiation Safety Officer

cc w/Encl 3: State of Connecticut

A. Lemay

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YALE-NEW HAVEN HOSPITAL - NRC INSPECTION NO. 03001244/2018001 AND NOTICE OF VIOLATION DATED September 14, 2018

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ENCLOSURE 3: NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, Connecticut

Docket No. 030-01244
License No. 06-00819-03

During an NRC inspection conducted on May 14-17, 2018 with continued in office review and exit on August 21, 2018, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.70 (a) requires, in part, a licensee shall survey with a radiation detection survey instrument at the end of each day of use.

Contrary to the above, for an undetermined length of time prior to May 2018, the licensee did not survey with a radiation detection survey instrument at the end of each day of use. Specifically, the Nuclear Medicine department at 20 York Street reported their practice as conducting their daily survey each morning prior to use.

- B. 10 CFR 35.610 (d) requires, in part, that a licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties in operating and emergency procedures; and 10 CFR 35.610 (e) requires, in part, that a licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures initially and at least annually.

Contrary to the above, in 2016 and 2017, the licensee did not provide instruction annually to all individuals who operate the unit, as appropriate to the individual's assigned duties in operating and emergency procedures and did not ensure that authorized users participate in drills of emergency procedures annually. Specifically, for the gamma knife facility, in 2016 three authorized users and in 2017 one authorized user did not participate in the annual training on operating, emergency procedures and the required drills of these procedures.

- C. 10 CFR 20.1101(c) requires, in part, that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, in 2016 and 2017, the licensee did not periodically (at least annually) review the radiation protection program content and implementation. Specifically, in 2016, only Nuclear Medicine and two satellite facilities were reviewed, and in 2017, only the gamma knife, the HDR and San Raphael's facilities were reviewed. This does not constitute a review of the radiation program content and implementation.

This is a Severity Level IV problem (NRC Enforcement Policy Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Yale-New Haven Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the

Notice of Violation

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corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 14 day of September 2018