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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD - SUITE 102
KING OF PRUSSIA, PA 19406-1415

March 25, 2025

EA-24-048/EAF-RI-2025-0080

Elizabeth Herbert
Vice President, Smilow Cancer Network
Yale-New Haven Hospital
20 York Street, NP5-207
New Haven, CT 06510

SUBJECT: YALE-NEW HAVEN HOSPITAL - NOTICE OF VIOLATION AND EXERCISE OF
ENFORCEMENT DISCRETION; NRC INSPECTION REPORT NO. 030-
36413/2024-001

Dear Elizabeth Herbert:

This letter refers to the inspection conducted on April 9, 2024, at your blood bank facility in New Haven, Connecticut. This inspection occurred following notification that the blood irradiator was to be removed. The inspection consisted of an examination of activities performed within the jurisdiction of the U.S. Nuclear Regulatory Commission (NRC), as they related to NRC-licensed byproduct material. Within this area, the inspection consisted of a selected examination of representative records, observations of activities, independent radiation measurements, and interviews with staff. Based on the results of the inspection, the NRC identified apparent violation(s) (AVs).¹ The violations are of a security-related nature; therefore, details of the violations were described in the non-public NRC inspection report (ML24323A112 ²) dated November 20, 2024. We note that Yale New Haven Hospital (YNHH) took immediate corrective actions to address the security related AVs. The nature of security related AVs and the corrective actions taken to address such issues are considered sensitive information and are not included in this letter but are described in the non-public enclosure.

Enclosures transmitted herewith contains sensitive unclassified non-safeguards information (SUNSI). When separated from enclosure, this transmittal document is decontrolled.

¹ Consistent with the NRC Enforcement Manual, Section 1.3.7.2 "Documentation Requirements," the number of Apparent Violations (AVs) involving NRC security-requirements cannot be disclosed. Consistent with the NRC's Plain Language approach to open government, the AVs will hereafter be referred to in the plural sense.

² Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS.

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In the letter transmitting the inspection report, we provided you with the opportunity to address the AVs identified in the report by either attending a pre-decisional enforcement conference or by providing a written response before we made our final enforcement decision. In a non-publicly available letter (ML25013A248) dated December 18, 2024, you provided a response to the AVs.

Based on the information developed during the inspection and the information that you provided in your December 18, 2024, response to the inspection report, the NRC has determined that one or more security-related violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) (Enclosure 1) and the circumstances surrounding them are described in detail.

The NRC has concluded that information regarding: (1) the reason for the violation(s); (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket in Inspection Report No. 030-36413/2024-001 and in your letter dated December 18, 2024. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions in the enclosed Notice.

In accordance with the NRC Enforcement Policy, a base civil penalty is considered for any escalated enforcement action that is not the first action within two years or two inspections for that entity. Additionally, credit to mitigate a civil penalty can be given for identification and corrective actions taken. Specifically, because Yale New Haven Hospital, under a separately held license, has been the subject of an escalated enforcement action within the last two years,³ the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC staff determined that credit for Identification is not warranted since the issue was identified by both the licensee and the NRC at the same time during the inspection, but that credit for corrective action is warranted.

Therefore, after consultation with the Director of the Office of Enforcement and based on the relevant circumstances of this case, the NRC is exercising discretion not to propose a civil penalty in accordance with Section 3.5 of the Enforcement Policy, "Violations Involving Special Circumstances." However, significant violations in the future could result in civil penalties. In addition, issuance of this escalated enforcement action may subject Yale New Haven Hospital to increased inspection effort. The NRC also includes significant enforcement actions on its website at <https://www.nrc.gov/about-nrc/regulatory/enforcement>.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice and

³ A Severity Level III violation with a \$9,000 civil penalty was issued on July 24, 2024 (EA-24-022) against license number 06-00819-03.

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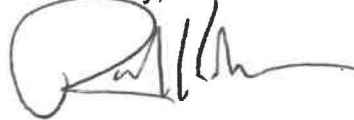
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Procedure", a copy of this cover letter will be available electronically for public inspection in the NRC's Public Document Room or from the Publicly Available Records (PARS) component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

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 Enclosure 1 will not be made available electronically for public inspection in the NRC Public Document Room or from ADAMS. If you choose to respond and Security-Related Information is necessary to provide an acceptable response, please mark your entire response "Security-Related Information in accordance with 10 CFR 2.390(d)(1)" and follow the instructions for withholding in 10 CFR 2.390(b)(1).

If you have any questions regarding this matter, please contact Monica Ford of my staff at (610) 337-5214, or via electronic mail at Monica.Ford@nrc.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Lorson', with a long horizontal flourish extending to the right.

Raymond K. Lorson,
Regional Administrator, Region I

Docket No. 030-36413
License No. 06-00819-05

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ADAMS ACCESSION NUMBER: **ML25080A049** (Cover letter w/o enclosure) (**Publicly Available**)
ADAMS ACCESSION NUMBER: **ML25080A006** (Cover letter w/SRI enclosure) (**Non-Publicly Available**)
DOCUMENT NAME: <https://usnrc.sharepoint.com/:w:/r/teams/Region-I-Enforcement-Files/Shared%20Documents/Proposed-Actions/Final%20Actions/EA-24-048 YNH NOV.docx>

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