



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD, SUITE 102
KING OF PRUSSIA, PA 19406-2713

July 24, 2024

EA-24-022

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

SUBJECT: NOTICE OF VIOLATION, EXERCISE OF ENFORCEMENT DISCRETION, AND PROPOSED IMPOSITION OF CIVIL PENALTY \$9,000 – YALE-NEW HAVEN HOSPITAL, NRC INSPECTION REPORT NO. 03001244/2024001

Dear Elizabeth Herbert:

This letter refers to the announced, reactive inspection conducted on January 10, 2024, at your facility in New Haven, Connecticut, with continued in-office review through April 5, 2024. The purpose of the inspection was to examine the circumstances involving the reported loss and subsequent recovery of a vial of licensed material on December 21, 2023. Based on the results of the inspection, the NRC identified two apparent violations (AVs) of NRC requirements. The NRC discussed the AVs with you during a telephonic exit meeting on April 5, 2024. The AVs were described in the NRC inspection report sent to you with a letter dated May 1, 2024 (ML24122A675).¹

The AVs were related to an event that occurred on December 14, 2023, when a nuclear medicine technologist (NMT) gathered lead vial containers from a storage drawer in the nuclear medicine hot laboratory in which the NMT believed that only empty lead vial containers were stored. One of those lead vial containers contained a vial with an unused dosage of approximately 44.67 millicuries of lutetium-177. These lead vial containers, including the one containing the unused vial, were placed into a cardboard box. The NMT performed a radiation survey but did not identify the presence of the unused vial. The box was transported to a waste facility that was authorized to dispose of the lead items but was not authorized to possess radioactive material. At the waste facility, the lead vial containers were moved by hand to another container for weighing. The radiation detector at the weigh scale did not alarm (indicating that the unused vial was still within a lead vial container at that point). The lead vial containers were then dumped into a larger aggregate container, at which point the vial is believed to have become unshielded.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

The aggregate container remained in a warehouse that had been secured with locks, a monitored after-hours alarm system, and a security fence until December 21, 2023. On that date, the container was loaded onto a truck and transported to the weigh scale where a radiation alarm indicated the presence of the radioactive material. Upon activation of the alarm, the waste facility contacted Yale-New Haven Hospital. The licensee's staff responded to the facility the same day and retrieved the material for proper disposal.

In the May 1, 2024, letter transmitting the inspection report, we informed you that the AVs were being considered for escalated enforcement action, including a civil penalty. In the letter, we provided you the opportunity to address the apparent violations identified in the report by either attending a pre-decisional enforcement conference, engaging the NRC in Alternative Dispute Resolution (ADR) mediation, or by providing a written response before we made our final enforcement decision.

In a letter dated May 28, 2024, (ML24162A055), you provided a response to the AVs and described the actions taken and planned by Yale-New Haven Hospital to address the issues that resulted in the AVs. Namely, after performing a review and analysis to determine the cause of the incident, Yale-New Haven Hospital developed a Standard Operating Procedure (SOP) for handling lead vial containers and shields; in addition, each nuclear medicine technologist was retrained on the practices for performing surveys. You also provided re-education to your staff on the expectations for escalating concerns to management. Yale-New Haven Hospital also labeled the location where empty lead vial containers were to be stored.

Based on the information developed during the inspection and the information provided in Yale-New Haven Hospital's May 28, 2024, response, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), and the circumstances surrounding them were described in detail in the subject inspection report.

As described above, the violations are related to the improper transfer of a vial of licensed material. Specifically, the first AV involved Yale-New Haven Hospital's failure to dispose of licensed material by transfer to an authorized recipient as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2001(a). The second AV involved Yale-New Haven Hospital's failure to monitor the radioactivity of byproduct material with no interposed shielding prior to disposal as required by 10 CFR 35.92(a)(1). The NRC considers the improper transfer of NRC-regulated material a significant regulatory concern because of the potential for exposure to members of the public (although, in this case, no actual exposure in excess of NRC public dose limits occurred). Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III (SL III) problem. The NRC Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9,000 is considered for this SL III problem. Specifically, because Yale-New Haven Hospital has not been the subject of any escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for corrective action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC staff determined that credit for corrective action is warranted. Namely, as noted above, Yale-New Haven Hospital developed a new SOP for handling lead vial containers and shields, conducted staff training, and improved the labeling of the lead storage area.

Although the NRC staff determined that corrective action credit was warranted, the staff noted that in accordance with Section 3.6.h of the NRC Enforcement Policy, enforcement discretion to apply a civil penalty should be considered for violations involving the loss of control of regulated material. The NRC staff considered that the material was at the unauthorized waste facility for a week before it was identified and retrieved for proper disposal. The NRC staff also considered that the material had become unshielded during this period, although based on dose estimates developed by the licensee and reviewed by NRC staff, no members of the public (including waste facility staff) handled the vial or were near it long enough to receive radiation exposure in excess of the public dose limits.

Therefore, to emphasize the importance of ensuring licensed material is properly controlled and transferred for authorized disposal, I have been authorized, after consultation with the Director, Office of Enforcement, to exercise enforcement discretion and issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$9,000 for the SL III problem. In addition, issuance of this Notice constitutes escalated enforcement action that may subject Yale-New Haven Hospital to increased inspection effort.

You may choose to pay the proposed civil penalty by submitting your payment, with the invoice enclosed to this letter, to the following address:

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

In addition, you may pay the proposed civil penalty in accordance with NUREG/BR-0254. When using NUREG/BR-0254 to pay the civil penalty, the invoice number should be used as the "enforcement action identifier" when submitting your payment through one of the approved methods listed in the brochure. The NRC may consider a request for additional time to pay the proposed civil penalty, including the option to enter into an installment agreement, if payment of the civil penalty as a lump sum in the required timeframe would pose a financial hardship. To request additional time to pay, you must submit a written request, with appropriate justification explaining your financial hardship, to NRCCollections.Resource@nrc.gov. All requests should be submitted in sufficient time to allow the NRC the ability to review your request for additional time to pay before the 30-day payment period expires.

If you disagree with this enforcement sanction, you may deny the violations, as described in the Notice, or you may request alternative dispute resolution (ADR) mediation with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral party (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Anne DeFrancisco, Chief, Medical and Licensing Assistance Branch at 610-337-5078 **within 10 days** of the date of this letter. You may also contact both ICR and Ms. DeFrancisco for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the time period for payment of the civil penalty and any required written response, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the corrective steps that have been taken and the results achieved; and (3) the corrective steps that will be taken; and (4) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03001244/2024001 and your letter dated May 28, 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 specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

If you have any questions concerning this matter, please contact Anne DeFrancisco of my staff at 610-337-5078 or Anne.DeFrancisco@nrc.gov.

Sincerely,

Raymond Lorson
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Civil Penalty Invoice
3. NUREG/BR-0254, "Payment Methods"

Docket No. 03001244

License No. 06-00819-03

cc w/ enclosures:

William A. Hinchcliffe III, Radiation Safety Officer
State of Connecticut

SUBJECT: NOTICE OF VIOLATION, EXERCISE OF ENFORCEMENT DISCRETION, AND PROPOSED IMPOSITION OF CIVIL PENALTY \$9,000 – YALE-NEW HAVEN HOSPITAL, NRC INSPECTION REPORT NO. 03001244/2024001: DATED

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RII, RIII, RIV (M Kowal; D Betancourt-Roldan, W Schaup)	
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ADAMS DOCUMENT ACCESSION NO.: ML24205A069 PACKAGE ACCESSION NO.:ML24205A061

DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\YNHH NOV-III-CP EA-24-022.docx

X SUNSI Review/ CJC		X Non-Sensitive □ Sensitive			X Publicly Available □ Non-Publicly Available	
OFFICE	RI/ORA	RI/DRSS	RI/ORA	RI/ORA	OE	NMSS
	M McLaughlin	A DeFrancisco	B Klukan NLO	J Nick	J Peralta	A Roberts
DATE	6/17/24	6/18/24	6/26/24	6/20/24	7/10/24	7/08/24
OFFICE	OGC NLO				RI/DRSS	RA
NAME	R Augustus				P Krohn	R Lorson
DATE	7/18/24				7/22/24	7/24/24

OFFICIAL RECORD COPY

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Yale-New Haven Hospital
New Haven, Connecticut

Docket No.: 03001244
License No.: 06-00819-03
EA-24-022

During an NRC inspection conducted between January 10, 2024, and April 5, 2024, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

1. 10 CFR 20.2001(a) requires, in part, that a licensee shall dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits in 10 CFR Part 20.

Contrary to the above, from December 14, 2023, through December 21, 2023, the licensee failed to dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits of 10 CFR Part 20. Specifically, on December 14, 2023, the licensee inadvertently transferred a vial containing approximately 44.67 millicuries of lutetium-177 to an unauthorized recipient. The licensed material was properly transferred for disposal on December 21, 2023.

2. 10 CFR 35.92(a)(1) requires, in part, that a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding.

Contrary to the above, on December 14, 2023, the licensee held byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity but did not monitor the byproduct material at the surface before disposal and determine that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding. Specifically, the licensee disposed of a lead vial container containing a vial of approximately 44.67 millicuries of lutetium-177 and did not monitor the vial at the surface with no interposed shielding before disposal.

This is a Severity Level III Problem (NRC Enforcement Policy Sections 2.3.4, 3.6.h, and 6.7). Civil Penalty - \$9,000

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03001244/2024001 and your letter dated May 28, 2024. However, if the description

therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a Reply to a Notice of Violation, and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Rd. Suite 102, King of Prussia, PA 19406, and the Document Control Desk, Washington, DC 20555-0001.

The Licensee may pay the civil penalty proposed above through one of the following two methods:

1. Submit the payment with the enclosed invoice for Civil Penalty EA-24-022, issued to Yale-New Haven Hospital, to the following address:

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

OR

2. Submit the payment in accordance with NUREG/BR-0254.

The Licensee may protest the imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the Licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282(c).

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, or Answer to a Notice of Violation, should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Rd. Suite 102, King of Prussia, PA 19406, and the Document Control Center, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request such material to be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 24th day of July, 2024.