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

May 1, 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: YALE-NEW HAVEN HOSPITAL NRC INSPECTION REPORT NO. 03001244/2024001 AND APPARENT VIOLATIONS

Dear Elizabeth Herbert:

This letter refers to the announced reactive inspection conducted on January 10, 2024, at your facility in New Haven, Connecticut, with an in-office review through April 5, 2024. The reactive inspection was focused on the State of Connecticut report to the Nuclear Regulatory Commission (NRC) on December 21, 2023, of a lost and subsequently recovered vial of licensed material. Within this area, the inspection consisted of a select examination of representative records, observations of activities, independent radiation measurements, and interviews with staff. The preliminary inspection findings and circumstances surrounding two apparent violations were discussed with you and your staff during a briefing on January 10, 2024, and during an exit meeting held remotely on April 5, 2024. The discussions included the significance of the issues, your corrective actions, and your preventative actions. The enclosed inspection report presents the findings of this inspection.

Based on the results of this inspection, the NRC identified two apparent violations (AVs) which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is available on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. These AVs involved the apparent failures to: (1) dispose of licensed material by transfer to an authorized recipient; and (2) monitor byproduct material waste with no interposed shielding prior to disposal.

We noted that you took immediate actions in response to the occurrence in order to restore compliance with NRC requirements. However, because these apparent violations involved the loss of control of licensed material, the NRC is considering proposing imposition of a civil monetary penalty. Section 2.3.4, Civil Penalty, of the Enforcement Policy states that for violations where a licensee has lost required control of its regulated licensed material for any period of time, the NRC normally will impose at least a base civil penalty. The NRC may exercise its discretion to mitigate or escalate a civil penalty amount based on the merits of a specific case. However, the NRC will not normally decrease the civil penalty to an amount below $9,000 for cases involving lost sources.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Before the NRC makes its enforcement decision, we are providing you an opportunity to offer your perspective on this matter and provide any information you believe the NRC should take into consideration. You can elect to provide such information by either: (1) responding to the apparent violations addressed in this inspection report within 30 days of the date of this letter, (2) requesting a Pre-decisional Enforcement Conference (PEC), or (3) requesting Alternative Dispute Resolution (ADR). **Please contact Anne DeFrancisco, Chief, Medical and Licensing Assistance Branch, NRC Region I, at 610-337-5078 or Anne.DeFrancisco@nrc.gov within 10 days of the date of this letter to notify the NRC which of the above options you choose**.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report No. 03001244/2024001; EA-24-022," and should include for each apparent violation: (1) the reasons for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. You should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalties for the apparent violations.

Additionally, your response should be sent to U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy mailed to Paul G. Krohn, Director, Division of Radiological Safety & Security, U.S. Nuclear Regulatory Commission Region I, 475 Allendale Road, Suite 102, King of Prussia, PA, 19406, and emailed to R1Enforcement@nrc.gov within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

If you choose to request a PEC, the meeting will be held within 30 days of the date of this letter. The conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The PEC would be open for public observation, and the NRC would issue a press release to announce the time and date of the conference.

In lieu of a PEC or written response, you may request ADR 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 mediator. The technique that the NRC has decided to employ is mediation; a voluntary, informal process in which a trained neutral 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 ADR program can be obtained 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 program as a neutral third party. Please contact ICR at 877-733-9415 within **10 days** of the date of this letter if you are interested in pursuing resolution of this issue through ADR. The ADR mediation session should be held within 45 days of the date of this letter. The mediation session would be closed to public observation, but the time and date would be publicly announced.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, 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 Agencywide Document Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

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

Sincerely,

PAUL KROHN

Digitally signed by PAUL KROHN
Date: 2024.05.01 14:55:55 -04'00'

Paul G. Krohn, Director
Division of Radiological Safety and Security

Docket No. 03001244
License No. 06-00819-03

Enclosure:
NRC Inspection Report 030-01244/2024-001

cc w/ enclosure:
William A. Hinchcliffe, III., Radiation Safety Officer

cc w/o Encls: State of Connecticut

SUBJECT: NRC INSPECTION REPORT 030-01244/2024-001 DATED MAY 1, 2024

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DOCUMENT NAME: https://usnrc.sharepoint.com/teams/Region-I-MLA/Inspection Reports/Inspection Documentation - Draft/EA-24-022 Yale Hosp Choice Letter and IR Final.docx
SUNSI Review Complete: JNguyen
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OFFICE	RI: DRSS	RI: DRSS	NMSS	OGC NLO	OE
NAME	Janice Nguyen	Anne DeFrancisco	Austin Roberts	Reginald Augustus	Sue Woods
DATE	4/28/24	4/28/24	4/29/24	4/30/24	4/30/24
OFFICE	RI: DRSS				
NAME	Paul Krohn				
DATE	5/1/24				

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Docket:	030-01244
License:	06-00819-03
Report:	2024-001
EA No.:	EA-24-022
Licensee:	Yale-New Haven Hospital
Location Inspected:	20 York Street, NP5-207 New Haven, CT 06510
Inspection Dates:	January 10, 2024 (Reactive), with in-office review through April 5, 2024

Inspectors: *Janice Nguyen* 5/1/2024
Janice Nguyen, Senior Health Physicist — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety and Security

Valerie Stowell 5/1/2024
Valerie Stowell, Health Physicist — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By: *Anne DeFrancisco* 5/1/2024
Anne DeFrancisco, Chief — Date
Medical & Licensing Assistance Branch
Division of Radiological Safety and Security

Attachment: Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Yale-New Haven Hospital
NRC Inspection Report 030-01244/2024-001

An announced reactive inspection of Yale-New Haven Hospital was initiated on January 10, 2024, with in-office review through April 5, 2024. The inspection was a limited examination of activities conducted under the U.S. Nuclear Regulatory Commission's (NRC) license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the NRC license. In addition, the inspection included review of the State of Connecticut report to the NRC on December 21, 2023, of a lost and subsequently recovered radiopharmaceutical dose. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

Program Overview

Yale-New Haven Hospital is authorized by the U.S. Nuclear Regulatory Commission Materials License No. 06-00819-03 as a medical broad scope licensee to use a variety of sealed sources and unsealed byproduct material for medical use, such as nuclear diagnostic and therapeutic activities, as well as research in humans, as authorized by Title 10 of the *Code of Federal Regulations* Parts 33 and 35. At the time of the inspection, the licensee had seven locations of storage and use. Only the main campus in New Haven, Connecticut, was inspected in association with the incident.

Inspection Findings

Two apparent violations of NRC requirements were identified. These included the apparent failures to: (A) dispose of a dose vial by transfer to an authorized recipient; and (B) monitor byproduct material at the surface before disposal with no interposed shielding.

Corrective Actions

Following the incident on December 14, 2023, through its discovery on December 21, 2023, the licensee conducted a comprehensive review of the incident. This review evaluated factors that may have contributed to the incident and its potential root causes. Based on the outcome of this review, the licensee created two new standard operating procedures for radioactive waste decay in storage and disposal, and for lead disposal. The licensee also trained their staff on these new procedures, which required each individual sign a written attestation after completion. These actions were taken to ensure the incident circumstances would not be repeatable in the future and to ensure the safe operation of its program.

REPORT DETAILS

1. Program Overview

1.1. Program Scope

Yale-New Haven Hospital (YNHH) is authorized by the NRC Materials License Number 06-00819-03 as a medical broad scope licensee to use a variety of sealed and unsealed byproduct material permitted by 10 CFR Parts 33 and 35, including Ge-68 sealed sources, Y-90 TheraSpheres and SIR-Spheres, Sr-90 IVB sealed sources, Mo-99/Tc-99m generators, Pd-103, I-125, and Cs-131 seeds for permanent brachytherapy, Cs-137 sealed sources, I-131 in any form, Gd-153 sealed sources, Am-241 sealed sources, Ra-223 in liquid form, Ir-192 in a High Dose Rate Remote Afterloader (HDR) unit, Co-60 in a Gamma Stereotactic Radiosurgery (GSR) unit, and Actinium-225. Storage and use of NRC-licensed byproduct materials was authorized at seven separate licensee locations.

The primary location of use was the Medical Center Campus, which housed one Nuclear Medicine Department with uses under 35.100 – 300, including Lu-177 Pluvicto™ and Lutathera®. This inspection was limited to the evaluation of the reported incident at the Medical Center Campus.

2. Observations and Findings for Reactive Inspection of December 14-21, 2023, Incident

2.1. Inspection Scope

The State of Connecticut made a report to the NRC on December 21, 2023, of an unused vial of Lu-177 Pluvicto™ that was recovered at a lead disposal site. At the time of discovery, the vial was estimated to be 21.7 mCi. In addition, several contaminated, empty lead pigs were also identified.

On December 21, 2023, the radiation alarm at the weigh scale indicated the presence of radioactive material on a truck leaving the lead disposal site. Staff at the facility used a radiation detector to locate the material, then reported the incident to the State of Connecticut Department of Energy and Environmental Protection (DEEP). DEEP responded to the lead disposal site, and conducted surveys of all areas where the vial and lead pigs were present on site. No contamination was found in the storage areas. Surveys of the lead pigs from YNHH indicated contamination with Lu-177, however the unused vial was not contaminated externally and had no indications of being damaged or used. Surveys of the vial indicated radiation levels of 80 milliroentgen/hour (mR/hr) on contact, 4 mR/hr at one foot from the unshielded vial, and the pig measured 136 µR/hr, with the vial within.

Based on the lot number of the vial, it was determined that the vial came from Yale-New Haven Hospital. CT DEEP contacted the Radiation Safety Officer (RSO) of YNHH, who retrieved the material and transported it back to YNHH the same day (December 21, 2023) in accordance with U.S. Department of Transportation regulations.

2.2. Observations and Findings

Over the course of the inspection, additional information was provided that clarified information provided in the initial report and provided confidence of limited incident consequences. Based on staff interviews at YNHH, it was determined that on December 14, 2023, a nuclear medicine technologist (NMT) gathered lead from a storage drawer in the nuclear medicine hot lab where he believed only empty lead pigs to be stored. One of those lead pigs contained the unused dosage of Lu-177, which was approximately 44.67 mCi at the time of the incident (decayed from 257 mCi as of November 27, 2023). These lead pigs, along with the unused vial, were placed into a sturdy cardboard box and surveyed, where readings indicated levels at background.

The NMT transported the box in the trunk of a car to a waste facility for lead disposal, which he had done on at least one previous occasion. Once delivered to the disposal facility, the pigs were moved by hand to another container for weighing. The radiation detector at the weigh scale did not alarm. The pigs were then dumped into a larger aggregate container for lead (which the licensee conservatively surmised may have been when the vial became unshielded). This aggregate container sat undisturbed in a warehouse secured with locks, a monitored alarm system after hours, and a security fence for one week. The closest occupied work area to the container was approximately 25 feet away which was staffed only when a customer comes onsite for drop-off transactions (otherwise, the waste disposal workers are in the facility yard area). On December 21, 2023, the aggregate container was loaded onto a truck, where the radiation alarm at the weigh scale indicated the presence of the radioactive material. DEEP and YNHH were contacted, and the material was retrieved and returned to YNHH for decay-in-storage.

YNHH performed a root cause analysis of the incident, and determined the incident occurred due to the licensee's lack of a formal, documented process for storage and handling of unused lead pigs and doses. As a result, an NMT stored an unused dose in a drawer that had previously been used for storing empty lead pigs and the drawer contents were disposed without any expectation that an unused dose could be within. The licensee has since developed a Standard Operating Procedure (SOP) for radioactive waste decay in storage and disposal, and another SOP for lead disposal. Each NMT will be instructed by the licensee on the new SOPs and will have to sign an attestation acknowledging their understanding and compliance with each SOP. The licensee created a corrective action plan documenting these items and for tracking completion. The licensee also labeled the hot lab drawer to specify it is for empty lead pig storage only.

2.3. Conclusions

The reactive inspection conducted on January 10, 2024, identified two apparent violations as escalated enforcement with a potential for a civil penalty (CP).

A. 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.

B. 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 pig 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.

3. Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on January 10, 2024, at the licensee's facility in New Haven, CT. The licensee acknowledged the findings presented and committed to implementing their corrective action plan. The NRC conducted a final exit briefing via teleconference with David Carlson, Ph.D., Director of Medical Physics and Radiation Safety Committee (RSC) Chair, as well as William Hinchcliffe, III, Radiation Safety Officer, and other members of the licensee organization on April 5, 2024. The licensee again acknowledged the findings presented and did not dispute any of the facts presented. Information was provided regarding the NRC's ongoing consideration of the imposition of a civil penalty.

SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Elizabeth Herbert, Vice President, Smilow Cancer Network
David Carlson, Ph.D., Director of Medical Physics, RSC Chair
William A. Hinchcliffe, III, Radiation Safety Officer
Nicole Nardecchia, Quality Improvement and Patient Safety Manager
Brian Patchell, Nuclear Medicine Technologist
David Facchini, Director of Radiology and Biomedical Imaging
Michele Pepe, Senior Manager, Nuclear Medicine & PET CT

INSPECTION PROCEDURES USED

IP 87103, Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
IP 87130, Nuclear Medicine Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-01244/2024-001-A	AV	10 CFR 20.2001(a) – Failure to dispose of a dose vial by transfer to an authorized recipient.
030-01244/2024-001-B	AV	10 CFR 35.92(a)(1) – Failure to monitor byproduct material at the surface before disposal with no interposed shielding.

LIST OF ACRONYMS AND ABBREVIATIONS USED

10 CFR	Title 10 of the *Code of Federal Regulations*
CT	State of Connecticut
CP	Civil Penalty
DEEP	Department of Energy and Environmental Protection
GSR	Gamma Stereotactic Radiosurgery (GSR)
HDR	High dose rate remote afterloader
mR/hr	milliroentgen/hour
NMT	Nuclear medicine technologist
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer
SOP	Standard Operating Procedure
YNHH	Yale-New Haven Hospital