



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
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KING OF PRUSSIA, PA 19406-1415

June 18, 2025

Elizabeth Herbert
Vice President, Smilow Cancer Network
Yale-New Haven Hospital
Radiological Physics - WWW 229
20 York Street, NP5-207
New Haven, CT 06510

SUBJECT: YALE-NEW HAVEN HOSPITAL NRC INSPECTION REPORT 030-01244/2024002
AND NOTICE OF VIOLATION

Dear Elizabeth Herbert:

This letter refers to the announced routine inspection conducted on April 22 through 26, 2024, at your York Street (Medical Center Campus, New Haven), Norwich, Shoreline, and St. Raphael's Campus locations, with additional in-office review through May 21, 2025. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules, 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, independent radiation measurements, and interviews with personnel. This inspection did not cover the escalated action issued under Inspection Report 030-01244/2024001 [Agencywide Documents Access and Management System (ADAMS) Accession No. ML24205A069]. The preliminary inspection findings were discussed with you and your staff following the conclusion of the on-site portion of the inspection on April 26, 2024. The enclosed report presents the results of this inspection. A final exit briefing was conducted by video teleconference on May 21, 2025, with Elizabeth Herbert, William Hinchcliffe, III, David Carlson, and others of your staff.

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

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice 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 response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

The enclosure(s) contains Sensitive Unclassified Non-Safeguards Information
Upon separation, this cover letter is DECONTROLLED.

E. Herbert

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Based on the results of this inspection, the NRC has also determined that three additional Severity Level IV violations of NRC requirements occurred. These violations are being treated as Non-Cited Violations (NCVs), consistent with Section 2.3.2 of the Enforcement Policy, because: the licensee identified the violations; the licensee corrected or committed to correcting the violations within a reasonable period of time by specific corrective actions committed to by the end of the inspection, including immediate corrective actions and comprehensive actions to prevent recurrence; the violations are not repetitive as a result of inadequate corrective action; and the violations are not willful. These NCVs are described in the subject inspection report.

If you contest the NCVs you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to the Regional Administrator, Region I; and the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," 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 ADAMS, accessible from the NRC website 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 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).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document 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, proprietary, or safeguards information so that it can be made available to the public without redaction.

E. Herbert

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If you have any questions regarding this matter, please contact Jonathan Pfingsten of my staff at (630) 829-9853 or via electronic mail at Jonathan.Pfingsten@nrc.gov.

Thank you for your cooperation.

Sincerely,

Farrah C. Gaskins, Acting Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

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

Enclosures:

1. NRC Inspection Report
030-01244/2024002 (Health and Safety - Public)
2. Notice of Violation for NRC License No.
06-00819-03 (Public)
3. NRC Inspection Report
030-01244/2024002 (Security - Non-Public)

cc w/ enclosures:

William Hinchcliffe, III, Radiation Safety Officer

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E. Herbert

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SUBJECT: YALE-NEW HAVEN HOSPITAL NRC INSPECTION REPORT 030-01244/2024002
AND NOTICE OF VIOLATION DATED JUNE 18, 2025

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**U.S. NUCLEAR REGULATORY COMMISSION
REGION I**

Docket: 030-01244

License: 06-00819-03

Report: 2024-002

Licensee: Yale-New Haven Hospital, Radiological Physics - WWW 229

Locations inspected: York Street (Medical Center Campus, New Haven), Norwich, Shoreline, and St. Raphael's Campus

Inspection dates: April 22 through 26, 2024, with in-office review through May 21, 2025

Inspectors: Jonathan Pfungsten, Senior Health Physicist
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Jason vonEhr, Senior Health Physicist
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Janice Nguyen, Senior Health Physicist
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Approved by: Farrah C. Gaskins, Acting Chief
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Attachment: Supplementary Information – Health and Safety

Enclosure 1

EXECUTIVE SUMMARY

**Yale-New Haven Hospital
NRC Inspection Report 030-01244 /2024-002 (Health and Safety)**

An announced routine inspection was performed of Yale-New Haven Hospital (YNHH) April 22 through April 26, 2024, with additional in-office review through May 21, 2025. The inspection was an examination of activities conducted under the U.S. Nuclear Regulatory Commission (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. Within these areas, the inspection consisted of a selected examination of written procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

Program Overview

YNHH is a medical broad scope licensee authorized by NRC License No. 06-00819-03 for a wide range of sealed and unsealed NRC-licensed byproduct material for medical diagnosis, therapy, and research in humans. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in New Haven, CT, Guilford, CT, North Haven, CT, and Norwich, CT.

Inspection Findings

Three violations of very low safety significance were identified concerning NRC health and safety requirements. The violations involved the failure to aggregate dose across multiple employers, failure to administer dosages within prescribed range or within 20 percent of prescribed dosage, and the failure to perform leak tests on approved intervals. The NRC's observations and findings are discussed in this report (Enclosure 1).

Additionally, three Non-Cited Violations (NCVs) meeting the conditions of Section 2.3.2 of the Enforcement Policy are discussed in this report, including for the failure to ensure a written directive was signed and dated prior to administration, failure to administer dosages within the prescribed range or within 20 percent of the prescribed dosage, and the failure to perform breakthrough testing for each eluate from a generator.

REPORT DETAILS – HEALTH AND SAFETY

1. Program Overview (IP 87133)

YNHH was a medical broad scope licensee authorized by NRC License No. 06-00819-03 for a wide range of sealed and unsealed NRC-licensed byproduct material for medical diagnosis, therapy, and research in humans. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in New Haven, CT, Guilford, CT, North Haven, CT, and Norwich, CT.

One amendment had been issued since the prior routine inspection (July 2022) which increased the Lu-177 possession limit to support increased patient volume for Lutathera and Pluvicto programs.

2. Observations and Findings

2.1. Inspection Scope

An announced routine inspection of YNHH was performed onsite April 22 through April 26, 2024, with additional in-office review through May 21, 2025. The scope of the inspection was to examine licensed activities as they relate to public health and safety and to the NRC's rules and regulations. Within these areas, the inspection consisted of a selected examination of written procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

2.2. Observations and Findings

The licensee had seven locations of use. The following locations were inspected: York St (Medical Center Campus, New Haven), Norwich, Shoreline, and St. Raphael's Campus (SRC).

The primary location of use is the Medical Center Campus. This location housed one Nuclear Medicine (NM) department with Positron Emission Tomography (PET), one Nuclear Cardiology department with Sr-82/Rb-82 cardiac PET, and one Radiation Oncology department with high dose-rate remote afterloader (HDR), gamma knife, Y-90, traditional brachytherapy (Title 10 of the *Code of Federal Regulations* (10 CFR) 35.400, though the eye plaque program had been dormant since May 2022), and intravascular brachytherapy (IVB, 10 CFR 35.1000). The NM department conducted diagnostic studies and a wide range of therapeutic treatments using unsealed byproduct material. This department received unit doses of various radionuclides from several vendors. The Nuclear Cardiology department received a Mo-99/Tc-99m generator weekly and possessed a Ruby-Fill Sr-82/Rb-82 generator. Radiation Oncology possessed and utilized Nordion Theraspheres, Sirtex SIR-spheres, Best Vascular A1000 IVB units, MDS Nordion GammaMedplus iX HDR unit, and a gamma knife unit.

Since the last inspection, the Radiation Safety Committee (RSC) had approved applications for five Authorized Users (AUs) and two authorized medical physicists (AMPs). In addition, they approved two new areas of use – a therapy suite for Lu-177 Pluvicto administrations and an area for I-131 albumen procedures. They also

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decommissioned one area at SRC that was no longer being used. The inspectors needed additional information to verify that one AMP met the requirements in 10 CFR 35.51(c) and that one AU was fully authorized based on a medical broad scope permit. The additional information was quickly obtained, and both individuals were fully qualified. All approvals were in accordance with NRC regulations.

Shoreline Medical Center performed sentinel node treatments and diagnostic cardiology studies using unsealed Tc-99m. Norwich performed diagnostic cardiology studies using unit doses of Tc-99m. SRC housed a small NM department and satellite Nuclear Cardiology department. As in the prior inspection, the licensee was no longer performing licensed activities at the Temple Medical Center.

The radiation safety program was run by a Radiation Safety Officer (RSO) who reported to a Vice President within the YNH system. The RSO had a staff of two full-time health physicists, though two additional staffers had recently been hired but had yet to onboard. The radiation staff performed the sealed source leak tests, inventories, radiation safety training, coordination of the dosimetry program, coordination of instrument calibrations (survey meters are calibrated by a vendor), therapeutic administration oversight (including room preparation and teardown, package receipt and assay/measurements), and general program support. The radiation safety staff also performed annual audits of the various locations, departments, and modalities within the program. The audits consisted of reviews of AUs/AMPs, training, dosimetry, postings, dose measuring equipment calibrations, dosage determinations, radiation protection, radiation surveys, radioactive waste, radioactive packages, written directives, and medical events. The previous inspection had identified that the licensee had failed to review the radiation safety program content implementation for the Radiation Oncology department since the prior inspection. This issue has since been corrected – both 2022 and 2023 included reviews of the various radiation oncology modalities (e.g., gamma knife, HDR).

The inspectors reviewed a sample of records related to the licensee's operations and recent therapies performed at each site inspected, including: audits; RSC minutes; patient dosage administrations; treatment plans; written directives; patient release instructions, calculations and/or surveys; daily area surveys; weekly area wipes; package receipt and return records; generator receipt/return records, and generator breakthrough testing; sealed source inventories and leak tests; dosimetry; waste disposal records; survey meter instrument calibrations; dose calibrator calibrations; radiation safety and Department of Transportation hazardous materials training, as applicable; operating, emergency, and security procedures; source exchange information; daily HDR spot checks; HDR full calibrations; brachytherapy seed inventories; and other treatment/modality specific documentation as described in the sections below. No medical events were identified by either the licensee or the NRC, aside from a medical event previously reported by the licensee and evaluated under Inspection Report 030-01244/2022002 (ADAMS Accession No. ML23062A338).

Independent and confirmatory radiation measurements were performed by the NRC throughout the inspection. Radiation levels were consistent with licensee postings, the quantity of radioactive material, and associated shielding.

As available, the inspectors observed treatments, material handling, and patient interactions for a variety of modalities at the locations inspected, as well as dosimetry

practices, equipment testing, surveys, wipes, waste management, and package receipt, as applicable. The inspectors interviewed the licensee staff on operating, emergency, and security procedures throughout the various programs.

All enforcement actions for deficiencies determined to be non-compliances are described in Sections 2.10 and 2.11 below.

2.3. Nuclear Medicine Programs – Various Locations

Yale-New Haven's main hospital location operated Monday through Friday from approximately 0630 – 1630. The NM department conducted diagnostic studies and a wide range of therapeutic treatments using unsealed byproduct material. This department received unit doses of various radionuclides from several vendors including, but not limited to, Cardinal Health (e.g., PET, Ga-68, Tc-99m, I-131), Novartis (e.g., Pluvicto, Lutathera), SOFIE (e.g., F-18), and PETNET (e.g., amyloid brain scans). The Nuclear Cardiology department received a Mo-99/Tc-99m generator weekly and possessed a Ruby-Fill Sr-82/Rb-82 generator. Nuclear Medicine Technologists (NMT) provided on-call weekend coverage. Cardiac rest/stress testing was performed for an average of 12 patients daily with Tc-99m obtained from an on-site generator. PET studies were performed for an average of 8 patients daily, including F-18 FDG and the department's Rb-82 generator. Both the generators and F-18 FDG doses were received from Cardinal Health.

Sealed source leak testing and inventories were performed by radiation safety. Prior to November 2023, the licensee was only performing Tc-99m generator breakthrough testing on a weekly basis. Per 10 CFR 35.204(b), each eluate of the generator must be tested for the concentration of molybdenum-99. However, since this was licensee identified and corrected, this is considered a NCV of 10 CFR 35.204(b) as noted in Section 2.11 below. Following identification by the licensee, each eluate was tested for the concentration of molybdenum-99. Independent surveys performed by the NRC in all areas of use were consistent with the licensee's measurements and were within regulatory limits.

The licensee's Norwich satellite cardiology department operated Monday, Tuesday, and Thursday from 0700 – 1530. One NMT who rotated to other satellite locations was on staff and treated 4-5 patients a day on average. Unit doses of Tc-99m were received from Cardinal Health on a twice daily basis. The facility consisted of one hot lab, one injection chair, one camera room, and one treadmill room. No concerns were noted during the inspection regarding the licensee's staff performance or with the NRC's records review.

The Shoreline facility operated Monday through Friday from 0630 – 1700. Seven NMTs total provided coverage for the satellite locations and rotate between facilities. On each day of operation, one or two NMTs provided coverage for the Shoreline facility and treated an average of four patients daily. Unit doses of Tc-99m were received through two daily runs from Cardinal Health. The department consisted of one hot lab, one injection area, one camera room, and one treadmill room. Additionally, there was a surgery center in the building which performed lymphoscintigraphy injections, which were assayed upon receipt in the cardiology department hot lab.

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During the review of patient administrations, the inspector noted that multiple Lymphoseek® injections were assayed significantly before the time of injection relative to the half-life of the material, therefore the administered amount recorded was not accurate to the actual activity administered. However, the licensee identified the issue in June 2023 and began updating their records to account for radionuclide decay between assay and administration time. This non-compliance was licensee identified and corrected; therefore, it is considered an NCV as noted in Section 2.11 below.

The SRC satellite location consisted of both a general nuclear medicine department and a cardiology department. While there was some overlap in areas of use, both departments operated separately and with different personnel.

The SRC cardiology department operated from 0630 – 1530 Monday through Friday, with no on-call or weekend hours. One NMT provided coverage for the department and treated an average of 3-4 patients daily, along with any in-patient add-ons. Unit doses of Tc-99m were received twice daily from Cardinal Health. Their areas of use consisted of two treadmill rooms, one gamma camera room, one shared hot lab, and one injection room shared with general nuclear medicine. The department received a new gamma camera in October 2022.

The SRC's nuclear medicine department operated Monday through Friday from 0700 – 1530, with on-call weekend coverage. Two NMTs staffed the department and treated approximately 3-5 patients daily using mainly In-111 and Tc-99m. Cardinal Health provided both unit and bulk doses to the department. The main studies performed were bone scans, HIDA scans, gastric emptying, ventilation-perfusion (V/Q) scans, and renal studies. The facility consisted of one camera room (separate from the cardiology camera room), one shared hot lab, one shared injection room, and one decay-in-storage room. The department obtained a new dose calibrator in October 2022.

During the review of patient administration records, the inspector noted multiple I-123 doses that were administered outside the licensee's AU approved dosage range. For this study, the approved dosage was 100 microcuries. Per 10 CFR 35.63(d), the licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. Contrary to this, the licensee administered dosages greater than 20 percent outside their approved prescribed dosage, with dosages of 156.9 microcuries administered in September 2023, 159.1 microcuries administered in October 2023, and 149.5 microcuries administered in January 2024. Additionally, multiple In-111 dosages were administered outside the approved dosage range of 0.45 – 1.1 microcuries, with dosages of 0.40 millicuries of In-111 administered in February 2023, 0.41 millicuries administered in December 2023, and 0.35 millicuries administered in March 2024. This is being considered a Severity Level IV violation of 10 CFR 35.63(d) as noted in Section 2.10 below.

2.4. 10 CFR 35.300 Program – Main Campus

The licensee maintained an active unsealed therapy and sodium-iodide I-131 program. The inspection included a review of the use of sodium-iodide I-131, Lu-177, and Ra-223. The inspectors reviewed a sampling of recent cases from each element of the program. The inspectors interviewed implementing staff and AUs, as well as reviewed written directives, patient release criteria and instructions, and ordering and receipt information.

With regards to sodium-iodide I-131, the licensee mostly utilized capsules, but had the infrastructure, equipment, and trained and experienced staff to perform liquid administrations, as needed. The licensee typically performed one to two lower-activity (5 mCi) I-131 administrations per month, and between four and six higher-activity (30-150 mCi) administrations per month. In each case, iodine administrations' written directives were complete, with minor questions on format and display of information being readily answered. Liquid iodine administrations were accompanied by a bioassay measurement for involved licensee staff, consistent with NRC Regulatory Guide 8.20 and the licensee's radiation safety program. Results of these bioassays were negligible in terms of measured intake and consistent with a well-functioning program. Patient release criteria were well documented and supported, and patient release instructions were consistent and equivalent to (or exceeding) published NRC guidance, including NRC Regulatory Guide 8.39, Revision 1.

With regards to Ra-223 Xofigo, the licensee used the radioisotope only sporadically – eight administrations were noted between July 2023 and April 2024, or approximately one per month. Written directives were appropriately completed, weight-based dosages were well documented, and implementing procedures were appropriate for the unique nature of the radioisotope. The inspectors interviewed the chief AU responsible for signing the recent written directives, as well as implementing staff. No concerns were identified, and no medical events or incidents were either reported by the licensee or identified by the inspectors.

With regards to Lu-177, the inspectors had an opportunity to observe an administration of Lu-177 Pluvicto. The inspectors observed the licensee staff prepare the equipment, test the infusion device, and draw up appropriate documentation to perform the administration. The observations included the drawing of the dose and the associated assay and found it consistent with the written directive and standard licensee procedures. The infusion device was brought to the patient's room, instructions were provided to the patient along with isolation instructions for release following the administration. The AU responsible for the administration discussed the procedure with the implementing staff and the patient and signed and dated the written directive prior to the infusion commencing. The infusion proceeded as planned, with no incidents or issues during the administration. The inspectors further reviewed prior Lu-177 cases, identifying no issues with administrations, procedures, or instructions to the patients. One concern was identified with regards to the patient release criteria, which is described below in Section 2.9.

The NRC reviewed a December 21, 2023, incident concerning the unintended disposal of a Lu-177 dosage as part of a separate inspection (030-01244/2024001, EA-24-022, ADAMS Accession No. ML24122A675). As a result, this incident was not reviewed under the current inspection (030-01244/2024002).

2.5. High Dose-Rate Remote Afterloader (HDR)

The licensee possessed a MDS Nordion Model GammaMedplus iX remote afterloader unit for medical therapy and research in humans. The majority of treatments were gynecological treatments utilizing cylinders.

The inspectors observed an HDR daily spot check, patient treatment planning, patient treatment, and post-treatment surveys. The inspector interviewed the technicians, AU, AMP, and radiation safety staff on their roles in operating, emergency, and security procedures relating to the HDR program.

The AU, AMP, and support staff were present during the initiation of treatment and remained through the entirety of the treatment observed. Radiation surveys were performed following the treatment but prior to the patient leaving the treatment vault.

The inspectors reviewed the daily spot checks, source exchanges and maintenance, full calibrations, written directives, maintenance records and survey records. The inspectors verified key security and access, proper emergency procedures and contact information were located at the console, emergency equipment is pre-staged, and interlocks were properly functioning,

The inspectors discussed the following observations with the licensee concerning the HDR program, though these did not constitute violations of NRC requirements:

- The daily spot checks were performed utilizing a prefilled form that essentially defaults to the successful condition. The inspectors noted that this may lead the staff to believe a section had already been successfully performed without actual completion. The inspectors recommended removing prefilled portions to ensure accurate results were captured. The AMPs were properly reviewing the results of spot checks. The inspectors interviewed the personnel responsible for performing the spot checks; the individuals were all knowledgeable of the procedures and requirements; no concerns were identified with the accuracy of the spot check results being documented.
- The spot check procedures tested all the necessary requirements per 10 CFR 35.643; however, some line items tested multiple functions without explicitly detailing each aspect. The inspectors recommended expanding the descriptions contained in the spot check procedures to adequately capture all the aspects being tested or verified.
- While observing the performance of the daily spot check procedure, the technician offered to demonstrate the treatment door interlock described in 10 CFR 35.615 and required to be tested under 10 CFR 35.643. However, at the time of the offer, the treatment door was open with an individual in the vault. The inspector spoke with the technician and radiation safety staff about the importance of performing this testing in a safe condition, without personnel in the vault who may be exposed if an error occurred. The licensee confirmed the required practice was to confirm the vault was empty during testing and treatments (except for the patient) and corrected the technician. The licensee and technician confirmed no testing had been performed with personnel in the vault.

2.6. Gamma Knife

The licensee possessed a gamma stereotactic radiosurgery unit licensed under 10 CFR Part 35 Subpart K. The inspection included a review of the device, its operation, routine periodic calibrations, and maintenance associated with the device. The inspectors were able to observe multiple patient treatments, including treatment planning, written directive preparation, and daily quality assurance/quality control measures. Licensee staff demonstrated the presence and operation of emergency and auxiliary equipment (i.e. audio/video equipment, area radiation detection equipment). The inspectors reviewed operating and emergency procedures, treatment planning and execution, and interviewed involved AMPs, AUs, and support staff. Regarding the radiosurgery unit, no license amendments were received or processed by the NRC since the last routine inspection performed in September 2020.

The licensee completed its most recent source reload for the radiosurgery unit in June 2020. The inspectors reviewed the licensee's nominal plans for the next reload, as well as a planned upgrade to the next model of the manufacturer's radiosurgery unit. The inspectors discussed with the RSO the licensing documentation that would be necessary to prepare and submit to the NRC to support the anticipated device upgrade. The NRC's updated licensing guidance on the radiosurgery units, published in May 2023 (ADAMS Accession No. ML23038A070), was shared with the licensee to consider during the anticipated unit upgrade, to consolidate their prior commitments and descriptions. This reload and unit upgrade was accomplished in October 2024 with NRC inspection oversight issued under Inspection Report 030-01244/2024-003.

The inspectors' review included the licensee's process improvements and procedure enhancements to address observations made during the September 2022 incident (Nuclear Materials Event Database (NMED) No. 220484) which involved a patient's helmet becoming loose and potentially impacting the intended treatment. The licensee's written report (ADAMS Accession No. ML22299A030) and the medical consultant (ADAMS Accession No. ML23003A785) concluded that, even under the worst-case scenario, no adverse medical impacts would result. The NRC's resulting reactive inspection (documented in a report dated March 6, 2023, ADAMS Accession No. ML23062A338) concluded that no violations of NRC requirements occurred. While it was deemed possible that unintended tissue may have been treated, it was concluded to be unlikely. Enhancements and improvements were discussed both in the licensee's written report as well as the NRC inspection report.

The licensee's descriptions and commitments related to the radiosurgery unit are contained across several license tie-downs following its upgrade in 2017 from the prior model of the radiosurgery unit (see License Condition (LC) 20.C through 20.G, and LC20.J). The inspectors reviewed the facilities, equipment, procedures, and other descriptions, representations, and commitments offered in these documents and found the licensee's program consistent with the content of these documents. Minor differences were noted with no material impact on treatment or operations in some documentation the licensee produced or retained.

The licensee utilized both fixed frame helmets mounted to the patient as well as heat-formed masks in the case of multiple fractions of treatment. An AMP walked through the treatment planning process from initial imaging, target planning, as well as the daily,

weekly, monthly, and annual checks on the device. The licensee maintained a preventative maintenance contract with the manufacturer, the last instance of which was performed in March 2024, and continued on a biannual basis. The inspector reviewed documentation related to training for involved physicists, physicians, and support staff, and interviewed individuals of each group. Support staff included nurses, radiation therapists, and ambulatory care assistants. The licensee typically performed multiple radiosurgery treatments each day, with approximately eight patients planned during the week of the inspection. The licensee's records documented 389 treatments in calendar year 2023, and 132 year-to-date for 2024 through the date of the on-site inspection. For the patient treatments performed while on-site, no issues were identified or concerns noted related to NRC requirements. No medical events were identified by the licensee or the inspectors in current or prior cases, a sampling of which were reviewed.

2.7. Yttrium-90 Microspheres

The licensee had a Y-90 microsphere program, including both TheraSpheres and SIR-Spheres. No treatments were planned nor performed during the week of the inspection, and therefore the review was limited to documentation and interviews with involved personnel. The licensee's records indicated that approximately 35 administrations were performed in calendar year 2022, 40 administrations in 2023, and 11 cases year-to-date in 2024. A sampling of these were reviewed by the inspectors. Three AUs were noted as having been involved and signed the written directives, one of whom was interviewed remotely. The AU described the treatment planning process, including ordering, assaying (as applicable), execution of the treatment, and post-treatment surveys and dose delivery determination. No medical events were identified by the inspectors nor by the licensee.

Two instances were identified where written directives were either not dated, or that the AUs signature and date were either typed or printed, and therefore unclear whether they were from an appropriately qualified AU. These two instances, in December 2022 and June 2023, were both identified by the licensee's own internal auditing process and captured in a written report from October 2023, prior to the NRC's inspection. These two instances were therefore dispositioned by the NRC as a single non-cited violation (see Section 2.11 below), as they were consistent with a Severity Level IV violation, licensee identified and corrected, non-repetitive and non-willful, per the NRC Enforcement Policy Section 2.3.2. The Severity Level IV determination is consistent with NRC Enforcement Policy Section 6.3.d.1, as the noncompliance was isolated in nature, not reflective of programmatic weaknesses, and did not cause a medical event.

2.8. Intravascular Brachytherapy

The licensee is authorized for the possession and use of Sr-90 for use in the Best Vascular, Inc., A1000 Series model IVB. The inspectors reviewed the licensee's IVB program, including procedures, written directives, security, training, leak tests, surveys, calibrations and maintenance.

The inspectors were able to observe a treatment in the operating room utilizing the device. The inspectors confirmed the proper controls were in place to confirm the patient's identity, verify the necessary information for the written directive, and verify the

treatment is performed in accordance with the written directive. A temporary storage container, known as a bailout box, was pre-staged for use if needed.

It was noted that, due to the emergent nature of the treatment and the patient's condition, the AU reviewed all the information and gave verbal approval for the written directive during a timeout in the operating room. This timeout was held prior to the initiation of the IVB treatment as the physicians made the decision of whether to proceed with the IVB treatment in real-time in the operating room, once equipment was in place and imaging had been performed. The AU then signed the documents after the procedure in accordance with 10 CFR 35.40(a)(1). The inspectors questioned the licensee whether the written directive could be signed prior to entering the operating room in order to avoid relying solely on verbal pre-approvals and to avoid sterilization concerns. The licensee agreed to consider this for future treatments.

2.9. Lu-177 Patient Release Criteria

One concern was identified with regards to patient release criteria associated with the Lu-177 program. Consistent with 10 CFR 35.75, the licensee had created an adequate model for determining the radiation exposure resulting from a single Lu-177 administration to a maximally exposed member of the public. However, Lu-177 treatments typically involve multiple administrations for each patient, and while each administration was separated by one to two months, patients commonly have multiple administrations within a calendar year.

In the NRC's review, the licensee would be able to readily permit patients to be released based on a cumulative exposure across the anticipated number of Lu-177 administrations, either without modification save for the aggregation of the patient release records, or with only minor adjustments to the patient release calculations or assumptions (e.g., extension of certain restrictions the patient was instructed to follow). As a result, the issue, as far as the licensee's scope of operations were concerned, involved only minimal health-safety consequence. Nonetheless, clarity was sought based on differing perspectives with licensee officials.

The inspectors reviewed NRC Regulatory Issue Summary (RIS) 2008-07 "Dose Limit for Patient Release Under 10 CFR 35.75," dated March 27, 2008 (ADAMS Accession No. ML063030572). The RIS states that:

"The Supplementary Information [accompanying the final rule (62 FR 3124, January 29, 1997)] states that [the 10 CFR 35.75] release limit was consistent with the recommendations of the International Commission on Radiological Protection (ICRP) in ICRP Publication 60, '1990 Recommendations of the International Commission on Radiological Protection,' and the National Council on Radiation Protection and Measurements (NCRP) in NCRP Report Number 116, 'Limitation of Exposure to Ionizing Radiation.'"

The RIS continues, stating that:

"If multiple administrations or applications in a single year are planned, anticipated, or potentially may be required for an individual, the decision about releasing that individual following each of the administrations should, in NRC's view, be based on

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the cumulative TEDE from all administrations or applications in a given year not exceeding 5 mSv (0.5 rem) for the maximally exposed other individual.

The position of the NRC, supported by the recommendations of both national and international organizations, remains that there should be an annual limit on the dose to other individuals from the release of an individual under the provisions of 10 CFR 35.75.”

The inspectors’ attention was also given to an apparently contradictory position published by the NRC in SECY-18-0015, dated January 29, 2018 (ADAMS Accession No. ML17279B140, part of overall ADAMS package ML17279B139). The SECY paper states that:

“The Statements of Consideration for the 1997 rule provide the clarification that the 5 mSv (0.5 rem) [Total Effective Dose Equivalent, TEDE] limit to an individual from exposure to the released patient is for each patient treatment. The broad consensus from the extensive stakeholder outreach conducted for the patient release evaluation is that the 1997 rule intended the limit to be applied on a per patient release basis. The NRC staff reaffirmed its determination that the limit for releasing patients who have been administered radioactive material applies to each individual treatment, and that based on the stakeholder feedback, rulemaking to make this clarification is not warranted. Some stakeholders suggested the limit should be an annual limit because the dose limits in 10 CFR Part 20 and the National Council on Radiation Protection and ICRP standards are annualized.”

The SECY paper does not mention RIS 2008-07, nor the basis for which the RIS derives its differing conclusion for an annualized limit. No additional published positions appear within the associated guidance documents by the NRC, such as NRC Regulatory Guide 8.39 (either the present Revision 1, dated April 2020, ADAMS Accession No. ML19232A081, or the Draft Revision 2, ADAMS Accession No. ML21326A168) or Information Notice 2017-02 “Best Practices in Patient Release” (ADAMS Accession No. ML17101A560).

The consideration of the apparent contradiction of published NRC positions without explicitly referencing and superseding or dismissing prior positions or withdrawing prior publications deemed out-of-date resulted in this concern being dispositioned as an observation only; no non-compliance was determined to have occurred.

2.10. Violations

2.10.1. No. 1: 10 CFR 20.1201(f)

The inspectors reviewed the licensee’s dosimetry program, including the process for issuing, tracking, and returning dosimeters, as well as the review of dosimetry data.

During these reviews, the inspectors identified that the licensee did not have a process for aggregating dosimetry data for their radiation workers who concurrently perform radiation worker duties under other NRC or Agreement State licenses. Instead, the licensee requested this information only from new employees during the onboarding

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process. The licensee confirmed that they did have individuals with occupational exposures from external employment that were not considered by the licensee.

As a result of the above, a violation of 10 CFR 20.1201(f) was identified. This violation is listed below (030-01244/2024-002-01).

10 CFR 20.1201(f) requires that the licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Contrary to the above, between July 11, 2022, and April 22, 2024, the licensee did not reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Specifically, the licensee solicited new employees for dose records in a given calendar from other employers but did not actively solicit current employees for dose from other sources of employment. The licensee confirmed that they did have individuals with occupational exposures from external employment that were not considered by the licensee.

This is a Severity Level IV violation (Enforcement Policy 6.7).

2.10.2. Violation No. 2: 10 CFR 35.63

The inspectors reviewed the administered dosages in comparison to the AU approved dosage ranges for the various types of studies performed by the Nuclear Medicine department at the Medical Center Campus (York St.). During these reviews, the inspectors identified that some of the newer protocols had not been added to the posted approved list. Upon further review, it was noted that most of these protocols and administrations received proper AU approval, though one example was identified without any AU approval. The protocol had been reviewed and approved by management, but not by any individual authorized as an AU under the appropriate category.

At the St. Raphael's Campus, I-123 injections were administered outside of the +/- 20% range for the licensee's AU approved dosage. For this study, the approved dosage was 100 microcuries. The licensee administered dosages of 156.9 microcuries in September 2023, 159.1 microcuries in October 2023, and 149.5 microcuries in January 2024. Additionally, multiple In-111 studies were administered outside the AU approved dosage range of 0.45 – 1.1 microcuries, with 0.40 millicuries of In-111 administered in February 2023, 0.41 millicuries administered in December 2023, and 0.35 millicuries administered in March 2024.

As a result of the above, a violation of 10 CFR 35.63(d) was identified. This violation is listed below (030-01244/2024-002-02).

10 CFR 35.63(d) requires that, unless otherwise directed by the authorized user, a licensee may not administer a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

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Contrary to the above, during calendar years 2023 and 2024, without being directed by the AU, the licensee administered dosages that did not fall within the prescribed dosage range or differed from the prescribed dosage by more than 20 percent. Specifically, at the Main Campus, for the biologically guided radiation therapy (BGRT) PET administrations, there was no AU approved prescription or dosage range. The protocol was approved by members of the appropriate department's management but was not approved by an AU despite being administered. For example, on March 22, April 2, and April 19, 2024, BGRT PET dosages of 15.67 mCi, 14.06 mCi, and 14.96 mCi, respectively, were administered. Additionally, at the St. Raphael's Campus, I-123 dosages differed from the prescribed dosage of 100 microcuries by more than 20 percent. The licensee administered dosages of 156.9 microcuries in September 2023, 159.1 microcuries in October 2023, and 149.5 microcuries in January 2024. Additionally, multiple In-111 studies were administered outside the approved dosage range of 0.45 – 1.1 microcuries, with 0.40 millicuries of In-111 administered February 2023, 0.41 millicuries administered December 2023, and 0.35 millicuries administered March 2024.

This is a Severity Level IV violation (Enforcement Policy 6.3).

2.10.3. Violation No. 3: 10 CFR 35.67

The inspectors reviewed the licensee's leak testing and inventory processes for sealed sources possessed at the various licensed locations. During these reviews, it was noted that the YNH radiation safety staff had identified that a leak test due in April 2023 was overdue for Co-60 sources utilized in a gamma knife unit. They worked with the Radiation Oncology department and external vendor to perform the leak test in August 2023. However, they failed to identify that the same issue repeated for the subsequent leak test which was due in February 2024 but not performed until March 2024.

As a result of the above, a violation of 10 CFR 35.67(b)(2) was identified. This violation is listed below (030-01244/2024-002-03).

10 CFR 35.67(b)(2) requires that licensees in possession of a sealed source shall test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

Contrary to the above, between October 4, 2022, and March 13, 2024, the licensee possessed sealed sources but failed to test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry. Specifically, the licensee's gamma knife Co-60 sources were not leak tested at the six-month frequency specified in the sealed source registration. The licensee performed a leak test on October 4, 2022, and identified that the leak test was due in April 2023, but did not perform the next 6-month leak test until August 14, 2023. The subsequent leak test was due February 14, 2024, but was not performed again until March 13, 2024.

This is a Severity Level IV violation (Enforcement Policy 6.7).

2.11. Non-Cited Violations (NCVs)

In addition to the violations identified in Section 2.10 above, the following NCVs are being documented. In each case, the NCVs would otherwise have been dispositioned as Severity Level IV violations and met the requirements of Section 2.3.2 of the Enforcement Policy, including being licensee identified and corrected, non-repetitive as a result of inadequate corrective action, and were non-willful.

2.11.1. Non-Cited Violation 2024-002-04 - 10 CFR 35.40(a)

10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material.

Contrary to the above, on December 20, 2022, a written directive was not dated and signed by an AU before the administration of any therapeutic dose of radiation from byproduct material. Specifically, the licensee performed a Y-90 microsphere administration without a proper AU signature or date on the written directive. The licensee identified the issue on October 3, 2023, during audits and had taken the following corrective actions: the licensee provided refresher training to the various interventional radiology AUs and provided training to staff involved in retaining and auditing the written directives, such as those in the radiation safety office. This was an isolated occurrence, did not demonstrate programmatic weaknesses in implementation, and did not result in a medical event.

2.11.2. Non-Cited Violation 2024-002-05 - 10 CFR 35.63

10 CFR 35.63 requires, in part, that a licensee shall determine and record the activity of each dosage before medical use. For a unit dosage, this determination must be made by direct measurement of radioactivity or a decay correction, based on the activity or activity concentration determined by a manufacturer or preparer licensed under 10 CFR 32.72 of this chapter or equivalent Agreement State requirements. Additionally, unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

Contrary to the above, the licensee failed to determine and record the activity of each dosage before medical use. For a unit dosage, the licensee failed to make this determination by direct measurement of radioactivity or a decay correction, based on the activity or activity concentration determined by a manufacturer or preparer licensed under 10 CFR 32.72 of this chapter or equivalent Agreement State requirements. Additionally, without otherwise being directed by the AU, the licensee used a dosage when the dosage did not fall within the prescribed dosage range, or the dosage differed from the prescribed dosage by more than 20 percent.

Specifically, at the Shoreline facility, sentinel node administrations were being performed with the dose being assayed when received by the department; however, the staff were not performing a decay correction to account for when the dose was actually administered.

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At Medical Center Campus (York St), sentinel node administrations were being performed without either direct measurement of radioactivity or a decay correction based on the activity determined by the radiopharmacy.

Additionally, based on the assays that were performed and recorded, several administrations were performed outside of the AU approved dosage range of 0.2-1.2 mCi without otherwise being approved by the authorized user.

The licensee identified the issues during routine audits, discussed the issues at numerous RSC meetings, and has taken the following corrective actions: each dose is required to be assayed at an appropriate time; the licensee implemented a timeout prior to administrations to reverify patient identity and dose; the timing of this timeout is noted in the procedure documentation and the dose is subsequently decay corrected to ensure the appropriate activity was administered or otherwise approved by an AU.

2.11.3. Non-Cited Violation 2024-002-06 - 10 CFR 35.204

10 CFR 35.204(b) requires that a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with breakthrough limits listed in 10 CFR 35.204(a)(1).

Contrary to the above, the licensee used molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical but failed to measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with breakthrough limits listed in 10 CFR 35.204(a)(1). Specifically, the licensee performed the required testing weekly based on a since-revised regulation. This issue was identified and corrected by the licensee in November 2023.

To correct this, the licensee began performing the tests each day with each elution. This change has been incorporated into their procedure.

2.12. Prior Violations for Review

The prior routine inspection (Inspection Report 030-01244/2022001) identified three violations of safety requirements.

2.12.1. Violation 2022-001-001 - 10 CFR 20.1101(c) – The licensee was previously cited for the failure to perform an annual review of the radiation safety program content and implementation for the irradiator license and the Radiation Oncology department under the broad scope license during the inspection period as required by regulation.

During this inspection, the inspectors reviewed the annual reviews of the various departments and locations performed by the YNHH radiation safety office. The issue concerning the failure to review the Radiation Oncology department has since been corrected. The licensee has been performing the required radiation oncology reviews and has developed and maintained a tracker for the various locations, departments, and modalities requiring review each year. This violation is closed.

- 2.12.2. Violation 2022-001-002 - 10 CFR 35.40(b)(7) – The licensee was previously cited for the failure to include the number of sources and the total source strength and exposure time (or the total dose) in the written directives for temporary manual brachytherapy in the form of Iodine-125 eye plaques, after implantation, but before completion of the procedure.

The inspectors reviewed the templates that are to be utilized for this purpose and noted that they had been revised in accordance with the regulations. However, there had not been any I-125 eye plaque manual brachytherapy procedures since the prior inspection. Therefore, this violation is being held open until the effectiveness of the corrective actions can be confirmed.

- 2.12.3. Violation 2022-001-003 - 10 CFR 35.63(d) – The licensee was previously cited for using dosages that did not fall within the prescribed dosage range, or the dosages differed from the prescribed dosage by more than 20 percent without being directed by the AU.

The inspectors reviewed the dosages administered since the prior inspection and determined that the issues had not been properly corrected. Specifically, the BGRT F-18 scans at Medical Center Campus were performed without an AU approved protocol or AU approved dosage. Additionally, I-123 and In-111 dosages at St. Raphael's Campus were identified as being administered outside of the approved range without proper AU approval. Therefore, this violation is being cited as a repetitive violation.

2.13. Conclusion

The NRC's inspection associated with YNHH's compliance with NRC health and safety requirements identified three violations associated with the failures to aggregate dose across multiple employers, failure to administer dosages within prescribed dosage ranges or within 20 percent of the prescribed dosage, and failure to perform leak tests on approved intervals. Additionally, three NCVs were identified and corrected by the licensee associated with the failure to ensure written directives were signed and dated prior to administrations, failure to administer dosages within prescribed dosage ranges or within 20 percent of the prescribed dosage, and the failure to perform breakthrough testing for each eluate from a generator.

3. **Exit Meeting Summary**

The NRC inspectors presented the preliminary inspection findings following the on-site inspection on April 26, 2024, at YNHH's facility in New Haven, CT. Following the April 2024 onsite inspection, the licensee acknowledged the observations and preliminary findings as presented, did not dispute the facts presented, and committed to formulating corrective actions. The NRC conducted a final exit briefing via teleconference on May 21, 2025, with YNHH representatives, including: Elizabeth Herbert, William Hinchcliffe, III, David Carlson, and others of the YNHH staff. The licensee again acknowledged the findings presented and did not dispute any of the facts presented.

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SUPPLEMENTARY INFORMATION – HEALTH AND SAFETY

PARTIAL LIST OF PERSONS CONTACTED

David Carlson, PhD, DABR, Director of Therapeutic Medical Physics, RSC Chair
Elizabeth Herbert, Vice President, Smilow Cancer Network
William Hinchcliffe, Radiation Safety Officer

INSPECTION PROCEDURES USED

87130 – Nuclear Medicine Programs
87132 – Brachytherapy Programs
87133 – Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs
87134 – Medical Broad-Scope Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-01244/2024-002-01	VIO	10 CFR 20.1201 – failure to aggregate dose across multiple employers
030-01244/2024-002-02	VIO	10 CFR 35.63 – failure to administer dosages within prescribed range or within 20 percent of prescribed dosage
030-01244/2024-002-03	VIO	10 CFR 35.67 – failure to perform leak tests on approved intervals
030-01244/2024-002-04	NCV	10 CFR 35.40 – failure to ensure written directive was signed and dated prior to administration
030-01244/2024-002-05	NCV	10 CFR 35.63 - failure to administer dosages within prescribed range or within 20 percent of prescribed dosage
030-01244/2024-002-06	NCV	10 CFR 35.204 – failure to perform breakthrough testing for each eluate from a generator

Closed

030-01244/2022-001-01	VIO	10 CFR 20.1101(c) – failure to perform annual review of the radiation safety program content and implementation
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Discussed

030-01244/2022-001-02	VIO	10 CFR 35.40(b)(7) - failure to include necessary information in written directives
030-01244/2022-001-03	VIO	10 CFR 35.63(d) - failure to administer dosages within prescribed range or within 20 percent of prescribed dosage

Enclosure 1: Attachment

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
AMP	Authorized Medical Physicist
AU	Authorized User
CFR	<i>Code of Federal Regulations</i>
HDR	High dose-rate remote afterloader
IVB	intravascular brachytherapy
LC	License Condition
NCV	Non-Cited Violations
NM	Nuclear Medicine
NMED	Nuclear Materials Event Database
NMT	Nuclear Medicine Technologist
NRC	Nuclear Regulatory Commission
PET	Positron Emission Tomography
RIS	Regulatory Issue Summary
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SRC	St. Raphael's Campus
YNHH	Yale-New Haven Hospital

NOTICE OF VIOLATION

Yale-New Haven Hospital
Radiological Physics - WWW 229
New Haven, CT

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

During an NRC inspection conducted on April 22 through 26, 2024, with additional in-office review through May 21, 2025, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1201(f) requires that the licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Contrary to the above, between July 11, 2022, and April 22, 2024, the licensee did not reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Specifically, the licensee solicited new employees for dose records in a given calendar from other employers but did not actively solicit current employees for dose from other sources of employment. The licensee confirmed that they did have individuals with occupational exposures from external employment that were not considered by the licensee.

This is a Severity Level IV violation (Enforcement Policy 6.7).

- B. 10 CFR 35.63(d) requires that, unless otherwise directed by the authorized user, a licensee may not administer a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

Contrary to the above, during calendar years 2023 and 2024, without being directed by the AU, the licensee administered dosages that did not fall within the prescribed dosage range or differed from the prescribed dosage by more than 20 percent. Specifically, at the Main Campus, for the biologically guided radiation therapy (BGRT) Positron Emission Tomography (PET) administrations, there was no authorized user (AU) approved prescription or dosage range. The protocol was approved by members of the appropriate department's management but was not approved by an AU despite being administered. For example, on March 22, April 2, and April 19, 2024, BGRT PET dosages of 15.67 mCi, 14.06 mCi, and 14.96 mCi, respectively, were administered. Additionally, at the St. Raphael's Campus, I-123 dosages differed from the prescribed dosage of 100 microcuries by more than 20 percent. The licensee administered dosages of 156.9 microcuries in September 2023, 159.1 microcuries in October 2023, and 149.5 microcuries in January 2024. Additionally, multiple In-111 studies were administered outside the approved dosage range of 0.45 – 1.1 microcuries, with 0.40 millicuries of In-111 administered February 2023, 0.41 millicuries administered December 2023, and 0.35 millicuries administered March 2024.

This is a Severity Level IV violation (Enforcement Policy 6.3).

Enclosure 2

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- C. 10 CFR 35.67(b)(2) requires that licensees in possession of a sealed source shall test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

Contrary to the above, between October 4, 2022, and March 13, 2024, the licensee possessed sealed sources but failed to test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry. Specifically, the licensee's gamma knife Co-60 sources were not leak tested at the 6-month frequency specified in the sealed source registration. The licensee performed a leak test on October 4, 2022, and identified that the leak test was due in April 2023, but did not perform the next 6-month leak test until August 14, 2023. The subsequent leak test was due February 14, 2024, but was not performed again until March 13, 2024.

This is a Severity Level IV violation (Enforcement Policy 6.7).

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 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 website. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publicly 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 18 day of June 2025.