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

July 19, 2023

EA-23-059

Janette Edwards, MPH, MBA,
Vice President of Operations
The Hospital of Central Connecticut
100 Grand Street
Administrative Offices
New Britain, CT 06050

SUBJECT: NRC INSPECTION REPORT 030-01250/2023-001

Dear Janette Edwards:

This letter refers to the announced inspection conducted on March 7-9, 2023, at your facilities in New Britain, Southington, and Plainville, Connecticut, with an in-office review through June 13, 2023. 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) 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. The preliminary inspection findings were discussed with you and your staff following the conclusion of the onsite portions of the inspection on March 7 and 8, 2023. A final exit briefing was conducted telephonically with you and representatives of your staff, including Gregory Hisel, Radiation Safety Officer, and George Pavlonnis, Associate Radiation Safety Officer, on June 28, 2023. The enclosed report presents the results of the inspection.

Based on the results of the inspection, the NRC identified six apparent violations (AV), the first of which is being considered for escalated enforcement action, including a civil penalty, in accordance with the NRC Enforcement Policy. The current Enforcement Policy is available on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. These AVs involved the apparent failures to: (1) monitor occupational exposure of an interventional radiologist; (2) assess occupational dose to twelve staff who had occupational duties outside of the Hospital of Central Connecticut that involved exposure to radiation; (3) ensure that byproduct material being decayed-in-storage had a physical half-life of less than 120 days and perform adequate monitoring of the byproduct material prior to disposal; (4) create and retain a record of each disposal of byproduct material via decay-in-storage; (5) confine the possession and use of byproduct material to the locations authorized in the license; and (6) provide commensurate training to staff involved in the disposal of byproduct material via decay-in-storage.

The enclosure provides a description of the AVs. Please be advised that the number and characterization of AVs described in the enclosure may change as a result of further NRC 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 (1) respond to the apparent violations addressed in this inspection report in writing within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC); or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference.

If you decide to participate in a PEC or pursue ADR, please contact Anne DeFrancisco at (610) 337-5078 or via email at Anne.DeFrancisco@nrc.gov within 10 days of the date of this letter. A PEC should be held within 30 days of the date of this letter and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report (030-01250/2023-001); EA-23-059" and should include for each apparent violation: (1) the reason 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 your response. 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 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.

In lieu of providing this written response, you may choose to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration by requesting a PEC to meet with the NRC. If you choose to request a PEC, the conference will afford you the opportunity 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 decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference 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. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509[1]).

[1] NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this report may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end. https://www.nrc.gov/docs/ML

Finally, 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. Mediation is 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's 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's 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.

In accordance with 10 CFR 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 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 G. Krohn Digitally signed by Paul G. Krohn
Date: 2023.07.19 08:45:43 -04'00'

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

Docket No. 030-01250
License No. 06-02388-01

Enclosure:
NRC Inspection Report 030-01250/2023-001

cc w/ enclosure:
J. Semancik, Director, Radiation Division
Connecticut Dept. of Energy and Environmental Protection
G. Hisel, Radiation Safety Officer
G. Pavlonnis, Associate Radiation Safety Officer

SUBJECT: NRC INSPECTION REPORT 030-01250/2023-001 – DATED JULY 19, 2023.

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ADAMS ACCESSION NUMBER: ML23179A172

☒SUNSI Review:	ADAMS:	☐ Non-Publicly Available	☒ Non-Sensitive	Keyword:
By: JEV	☒ Yes ☐ No	☒ Publicly Available	☐ Sensitive	N/A

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DATE	06/29/23	06/29/23	06/28/23	07/05/23	07/11/2023	07/11/2023
OFFICE	RI:DRSS	RI:DRSS				
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DATE	07/13/23	07/19/23				

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Docket:	030-01250
License:	06-02388-01
Report:	2023-001
EA No.:	EA-23-059
Licensee:	The Hospital of Central Connecticut
Locations Inspected:	100 Grand Street, New Britain, CT 183 North Mountain Road, New Britain, CT 201 North Mountain Road, Plainville, CT
Inspection Dates:	March 7-9, 2023, with in-office review through June 13, 2023

Inspectors:

Jason vonEhr 06/28/2023
Jason vonEhr, Senior Health Physicist Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Netra Patel 06/29/2023
Netra Patel, Health Physicist Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Michael Wutkowski 06/29/2023
Michael Wutkowski, Health Physicist Date
Commercial, Industrial, Research and Development,
and Academic Branch
Division of Radiological Safety & Security

Approved By:

Christopher Cahill /for/ 07/13/2023
Anne DeFrancisco, Chief Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Attachment: Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

The Hospital of Central Connecticut
NRC Inspection Report 030-01250/2023-001

A routine announced inspection was performed at the Hospital of Central Connecticut on March 7-9, 2023, with in-office review through June 13, 2023. The inspection was an examination of activities conducted under the NRC license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's rules, regulations, and with the conditions of the NRC 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.

Program Overview

The Hospital of Central Connecticut was authorized by the U.S. Nuclear Regulatory Commission Materials License No. 06-02388-01 to use a variety of sealed and unsealed byproduct material for medical use, including diagnostic and therapeutic uses authorized by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100-300, 35.600, as well as emerging medical technologies under 10 CFR 35.1000. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in and around New Britain, Connecticut. (Section 1)

Inspection Findings

Six apparent violations of NRC requirements were identified. These apparent violations included the apparent failures to: (1) monitor occupational exposure of an interventional radiologist; (2) assess occupational dose to twelve staff who had occupational duties outside of the Hospital of Central Connecticut that involved exposure to radiation; (3) ensure that byproduct material being decayed-in-storage had a physical half-life of less than 120 days and perform adequate monitoring of the byproduct material prior to disposal; (4) create and retain a record of each disposal of byproduct material via decay-in-storage; (5) confine the possession and use of byproduct material to the locations authorized in the license; and (6) provide commensurate training to staff involved in the disposal of byproduct material via decay-in-storage.

Corrective Actions

The licensee performed a reconstruction to address the apparent gap in the occupational exposure records for the affected interventional radiologist. The licensee has not yet communicated its actions, planned or completed, to address the consistent and accurate monitoring of occupational exposure in the future to ensure durable and lasting compliance with the associated regulatory requirement. Further actions concerning apparent violation No. 2 identified above are described in Section 3.8.2 and No. 3-6 in Section 3.8.3 of this report.

REPORT DETAILS

1. Program Overview (Inspection Procedure 87130 and 87132)

1.1. Program Scope

The Hospital of Central Connecticut (HOCC) was authorized by the U.S. Nuclear Regulatory Commission (NRC) Materials License No. 06-02388-01 to use a variety of sealed and unsealed byproduct material for medical use, including diagnostic and therapeutic uses authorized by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100-300, a High Dose Rate Afterloader (HDR) under 10 CFR 35.600, as well as emerging medical technologies in the form of yttrium-90 microspheres under 10 CFR 35.1000. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in New Britain, Southington, and Plainville, Connecticut.

The license was amended three times since the NRC's last routine inspection (started on March 5, 2021). These amendments included:

- Amendment No. 121, issued on November 22, 2021, which removed two Authorized Users (AU) and a medical physicist from the NRC license, removed the authorization to use radioactive materials for manual brachytherapy under 10 CFR 35.400, and added a new location of use within HOCC's facilities;
- Amendment No. 122, issued on December 3, 2021, which authorized a change in the NRC-approved Radiation Safety Officer (RSO) and removed the self-shielded irradiator from the NRC license; and
- Amendment No. 123, issued on February 7, 2023, renewed the NRC license, changed the RSO, and added an Associate Radiation Safety Officer (ARSO).

1.2. Inspection Scope

The inspection was an examination of activities conducted under the 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 HOCC 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.

The inspection included a review of the findings, root cause(s), and corrective actions from the NRC's last routine inspection, as documented in Inspection Report No. 030-01250/2021-001, which resulted in escalated enforcement.

2. Review of Inspection Report No. 2021-001 Escalated Enforcement Findings

The NRC issued its report for Inspection Report No. (IR) 2021-001 on September 15, 2022 (redacted public version found at ADAMS Accession No. ML22258A099[2], nonpublic version at Accession No. ML22258A097), and revised the report on January 23, 2023 (public version: Accession No. ML23023A111, nonpublic version: Accession No. ML23023A106), in response to HOCCs written response dated

[2] NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this report may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end. https://www.nrc.gov/docs/ML

October 21, 2022 (nonpublic document: Accession No. ML22336A183). The NRC issued its final enforcement action on January 24, 2023 (public version: Accession No. ML23024A024, nonpublic version: Accession No. ML22314A103).

The enforcement action described above involved one or more violations of NRC security requirements that were categorized at Severity Level III. The NRC action stemmed from the licensee's failure to comply with requirements involving a category 2 quantity of radioactive material, as defined in 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." The NRC performed a non-routine, limited scope inspection on September 22, 2021 (IR2021-002, ADAMS Accession No. ML21326A047), which provided oversight of HOCC's transfer of the category 2 quantity of radioactive material to the Department of Energy. This material triggered HOCC's need to comply with the 10 CFR Part 37 requirements, and therefore, with its removal, HOCC was no longer responsible for the requirements in 10 CFR Part 37. The HOCC NRC license was amended on December 3, 2021, to remove the authorization to possess this material.

As a result of all the above, the NRC is closing all violations issued under IR2021-001, as the requirements therein are no longer applicable to HOCC's operations. These closures are further noted in this enclosure's attached Supplemental Inspection Information.

3. Observations and Findings

3.1. Locations Inspected and Licensee Oversight

This inspection included observations, interviews with staff, and select review of records and procedures at the 100 Grand Street, New Britain, Connecticut facilities (New Britain General Campus) and the satellite facility located at both 183 North Mountain Road, New Britain, and 201 North Mountain Road, Plainville, Connecticut (Radiation Oncology Treatment Center). The inspection did not address the licensed location located at 81 Meriden Ave, Southington, CT (Bradley Memorial Campus), as a result of the lack of licensed activities.

The inspectors toured all areas where licensed material was used or stored at the New Britain General Campus and the Radiation Oncology Treatment Center. This included but was not limited to observations of initial package receipt, dose calibrator quality control, dose preparation, administration, patient interaction, performance of radiation surveys, and radioactive waste management. Additionally, independent radiation surveys were performed and found to be consistent with licensee postings and within regulatory limits.

The radiation safety program operated under the direction of a Radiation Safety Committee (RSC) which met quarterly and included the representation required by 10 CFR 35.24. During the inspection period, the RSO changed from an onsite AU, who received the support of an ARSO, and a physics consultant who performed quarterly audits. The audits included, but were not limited to: equipment calibration, review of written directives, training, general records review, exposure evaluations, and the performance of sealed source leak tests and physical inventory.

3.2. Nuclear Medicine Operations – Imaging and Diagnostic

The inspector performed a sample review of records, polices, and procedures as they related to the licensee's nuclear imaging and diagnostic operations authorized under 10 CFR 35.100 and 10 CFR 35.200. The Nuclear Medicine Department had two full-time and two per diem Nuclear Medicine Technologists (NMT). One of the full-time NMT and one per diem NMT rotate at the cancer center. The licensee used technicium-99m to perform cardiac stress testing. The licensee imaged approximately nine to fifteen patients per day. PET/CT (Positron Emission Tomography/Computed Tomography) scans were only performed at the cancer center. The licensee used fluorine-18 and gallium-68 to perform PET scans. All the dosages were received from Cardinal Health as unit doses, except technicium-99m which was received as bulk doses. All doses were assayed prior to administration. The licensee also performed iodine-123 uptake studies with approximately four patients per quarter. During the course of the review of the licensee's imaging and diagnostic operations, four apparent violations were identified concerning the handling of unanticipated radioactive waste, which is discussed in Section 3.8 below.

3.3. Nuclear Medicine Operations – Therapeutic

The inspectors reviewed the licensee's nuclear unsealed therapeutic operations. The inspectors found that the licensee had not performed any recent radium-223 Xofigo administrations. The licensee provided the most recent administration, which occurred prior to the last routine inspection. No other cases occurred in that time period, and none were performed during the inspection. The licensee also performed therapeutic iodine-131 administrations. These ranged from treatments for hypothyroidism through thyroid ablations. The licensee performed four administrations in calendar year 2023 through the date of the inspection, including two ablations utilizing approximately 150 mCi of iodine-131.

No administrations were scheduled while the inspectors were onsite. All iodine-131 administrations were performed on an outpatient basis. The licensee provided sufficient patient release instructions and performed adequate patient release exposure calculations pursuant to 10 CFR 35.75. A sample of written directives representing recent iodine administrations was reviewed, with no issues or concerns identified.

3.4. Manual Brachytherapy

The inspectors did not review the licensee's now-terminated manual brachytherapy. The NRC license was amended on November 22, 2021, to remove the AUs and authorization for the 10 CFR 35.400 manual brachytherapy program. As a result, no inspection effort was expended on the activities performed between the last NRC inspection, which started remotely on March 6, 2021, and continued with an onsite inspection on March 21, 2021, and the termination of authorization for the program on November 22, 2021.

3.5. Remote Afterloader Brachytherapy

The inspectors performed interviews and reviewed select records, policies, and procedures as they related to the licensee's remote afterloader brachytherapy program authorized under 10 CFR 35.600. The licensee possessed a single Elekta Model

microSelectron 106.990 HDR remote afterloader. The licensee demonstrated its activities associated with this unit, including pre-treatment spot checks, periodic full calibration, use during patient treatment, security of the device and its associated keys, and availability of emergency response equipment. The licensee averaged between 130 and 140 treatments per year with this system. No patients were scheduled for treatment the week the inspection was performed, and as a result no observations were able to be made. The licensee was able to provide a walkthrough demonstration in order to facilitate a general overview of a procedure. No issues or items of concern were identified with respect to the licensees remote afterloader brachytherapy program.

3.6. Yttrium-90 Microsphere Program

The inspectors performed a review of records, policies, and procedures as they related to the licensee's yttrium-90 microsphere program authorized under 10 CFR 35.1000. The licensee utilized the BWXT Medical Ltd. Model Therasphere for the performance of its administrations. The licensee's single AU for this type of activity was not onsite during the inspection and was interviewed telephonically after the onsite inspection. The licensee's yttrium-90 program performed eight administrations in calendar year 2021, ten in 2022, and a single administration in year-to-date 2023 (through the date of the onsite inspection). The licensee was committed to the NRC's Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance (Revision 10.2, dated April 20, 2021), which is accessible at Accession No. ML21089A364. During the course of the review of the licensee's yttrium-90 program, one apparent violation was identified concerning the occupational monitoring of the AU, which is discussed in Section 3.8 below.

3.7. Independent Radiation Surveys

The inspectors performed independent radiation surveys throughout the inspection in areas of use or storage of radioactive materials, and included, but were not limited to: the administration rooms in the nuclear medicine suite, radioactive waste areas, radiopharmacy packages post-delivery, and the HDR unit. The survey results were generally consistent with the licensee's postings and applicable regulatory limits. One item was discussed with the licensee concerning a posting for the HDR, specifically the storage location storage for the HDR (an annex within the treatment room). HOCC had posted this area with "Caution: Radiation Area," despite the room not plausibly exceeding the 5 millirem in any one hour at 30 centimeters from the surface of the HDR as described in 10 CFR 20.1902(a) and as defined in 10 CFR 20.1003. The licensee explained that this was in case of emergency, rather than the expectation of meeting or exceeding the 10 CFR Part 20 requirement for posting this level of hazard during the course of routine operations. The licensee was encouraged to ensure that their postings were comparable and commensurate with the associated radiation hazard, and to not 'over-post' a room or area.

The inspectors' surveys were performed with a: Ludlum Model 2401-P, serial number 145164, calibration date November 3, 2022; Ludlum 2401-P, serial number 285217, calibration date January 05, 2023; and Ludlum 2401-P serial number 281353, calibration date September 19, 2022.

3.8. NRC Findings

Over the course of the NRC's observations, three areas of concerns were identified, resulting in six apparent violations. The first area of concern involved the licensee's occupational exposure monitoring program as it applied to a single interventional radiologist and AU. The second area of concern involved the licensee's monitoring for individuals with exposure external of the license. The third area of concern involved the licensee's handling of unanticipated radioactive waste that was identified in its non-radioactive waste streams.

Within the areas of concern identified above, six apparent violations of NRC requirements were identified. These apparent violations included the apparent failures to: (1) monitor occupational exposure of an interventional radiologist; (2) assess occupational dose to twelve staff who had occupational duties outside of the HOCC that involved exposure to radiation; (3) ensure that byproduct material being decayed-in-storage had a physical half-life of less than 120 days and perform adequate monitoring of the byproduct material prior to disposal; (4) create and retain a record of each disposal of byproduct material via decay-in-storage; (5) confine the possession and use of byproduct material to the locations authorized in the license; and (6) provide commensurate training to staff involved in the disposal of byproduct material via decay-in-storage.

These areas of concern and associated apparent violations are described in detail in Sections 3.8.1-3.8.3 below.

3.8.1. Occupational Exposure Monitoring (AV1)

During a review of HOCC dosimetry, an AU (an interventional radiologist) for yttrium-90 microspheres was identified as having abnormal dosimetry results. This included 16 months in Calendar Years (CY) 2021 and 2022 with no radiation exposure results at all, and three further months with exceptionally low radiation exposure results in contrast to the type and frequency of work with both radioactive material and machine-produced radiation. The machine-produced radiation was from the practice of interventional radiology and, primarily, the use of a fluoroscope.

The licensee reviewed the subject dosimetry results and agreed that they did not accurately reflect this AU's true occupational exposure and, as a result, took steps to perform a dose reconstruction. This dose reconstruction was based on the amount of time with the fluoroscopic beam on and combining this with academic literature in order to estimate the occupational exposure to the individual. The literature the licensee used suggested an exposure rate, as a result of scatter radiation from the fluoroscope, of between 3 millirem/minute of beam time for the fluoroscope (with a lead shield skirt on the patient's table) and 6 millirem/minute (without this lead shield). As a result, the licensee concluded that the AU experienced a radiation exposure of between 1,082 – 2,164 millirem for CY2021, and between 1,400 – 2,800 millirem for CY2022. This estimate was compared to the five months in CY2021 and CY2022 where the individual's dosimetry results appeared to be reasonable and potentially representative

of the interventional radiologist's actual exposure. This comparison suggested the licensee's academic literature-based estimate was reasonable: these five months' dosimetry results suggested a per-minute radiation exposure from a low of 2.35 millirem/minute of beam time to 6.17 millirem/minute of beam time, with an overall weighted average of 3.64 millirem/minute of beam time.

While this AU performed work at two other facilities, these facilities were within the overall Hartford HealthCare system, and the Hartford HealthCare system demonstrated during the inspection that it appeared to adequately aggregate occupational radiation exposure from facilities within its purview. Furthermore, these other two facilities contributed only very minor exposures to the AU's overall occupational exposure (the AU works 1 day every 2 months at the first facility, and 1 day every 6 months at the second). The AU and licensee confirmed that there was separately-issued dosimetry from each facility and the corporate Hartford HealthCare primary dosimetrist demonstrated how these were aggregated across the different Hartford HealthCare facilities.

In addition to the efforts described above, the licensee planned to provide extra dosimetry for an 8-week trial period after the inspection (starting in June 2023). This dosimetry would be provided to the AU with additional measures by the licensee to provide high confidence in the consistent and accurate wearing of this dosimetry. The purpose of this trial period was to supplement the academic literature and existing occupational exposure results in order to provide confidence in and narrow the estimated range of the final reconstructed occupational exposure result. As of the date of this report, the trial had not yet concluded. HOCC provided communications to the NRC regarding this reconstruction on April 13, 2023 (ADAMS Accession No. ML23166A148), which was revised following NRC input on April 18, 2023 (ADAMS Accession No. ML23166A149).

As a result of the gap identified between the AU's likely occupational exposure and what was recorded and reported by the individual's dosimeter, and the dosimetry program's apparent failure to identify the abnormal results in order to take compensatory measures, an apparent violation of 10 CFR 20.1502 was identified and is described below (030-01250/2023-001-01):

Apparent Violation No. 1: Occupational Monitoring

10 CFR 20.1502(a)(1) requires that each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits in 10 CFR Part 20. At a minimum, each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year form sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, from at least March 24, 2021, through March 6, 2023, the licensee failed to monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits in 10 CFR Part 20. Specifically, the licensee failed to monitor an interventional radiologist's exposure to radiation from radioactive materials and unlicensed radiation sources under the

control of the licensee, and the subject interventional radiologist's reconstructed radiation exposures were in excess of the 10 CFR 20.1201(a)(1) 10% threshold to require monitoring.

As a result of the estimated dose provided by HOCC at the time of this report's writing and potential for the AU to exceed NRC regulatory requirements for annual occupational dose, this AV is being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy.

3.8.2. External Occupational Exposure Monitoring (AV2)

HOCC had staff, contractors, and physicians who were exposed to radiation from NRC-licensed radioactive materials under the HOCC NRC license who were also exposed to radiation as part of their occupational duties from both unlicensed sources of radiation at HOCC as well as licensed and unlicensed sources of radiation at other Hartford HealthCare system facilities. In the examples reviewed and discussions with knowledgeable staff, HOCC appeared to have systems in place to collect and aggregate monitored occupational radiation exposure from other facilities within the Hartford HealthCare network. However, the licensee did not appear to have considered the need to collect and aggregate occupational radiation exposure that occurs outside this network.

Several staff were identified by the inspectors who worked under the scope of the HOCC NRC license in addition to facilities external to the Hartford HealthCare network. The occupational exposures experienced by these staff at these outside facilities was not aggregated into the radiation monitoring records or accounted for in the licensee's implementation of its radiation safety program.

Following identification by the NRC, HOCC worked to identify which staff, contractors, and physicians may be impacted by this gap in the monitoring program. Twelve individuals were identified by HOCC as having occupational exposure to radiation occurring outside of the HOCC and Hartford HealthCare network. At HOCC, this impacted eight staff in radiation oncology and four staff from nuclear medicine (which included PET).

Once identified, HOCC contacted each of the external facilities to share occupational exposure information, with the consent of the impacted individuals (as these records are generally protected from public disclosure under 10 CFR 20.2106(d) because of their personal privacy nature). In no instance was staff, following aggregation of other third-party entities, exposed to more than the NRC regulatory limits in 10 CFR 20.1201.

The magnitude of the external exposure that was unaccounted for by HOCC ranged from no recorded (or 'minimal') exposure, which is common and reasonable in routine radiation oncology operations, to 233 millirem whole body and 595 millirem extremity for the nuclear medicine staff. The licensee's initial outreach and final conclusions were documented in letters to the NRC dated April 13, 2023 (ADAMS Accession No. ML23166A147) and May 12, 2023 (redacted to protect privacy information, ADAMS Accession No. ML23166A151).

As a result of all the above, an apparent violation of 10 CFR 20.1201(f) was identified and is described below (030-01250/2023-001-02):

Apparent Violation No. 2: External Occupational Monitoring

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, in twelve instances from at least March 24, 2021, and March 6, 2023, the licensee failed to 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, for twelve individuals who performed licensed activities under the NRC license, the licensee failed to assess occupational dose received while the individuals continued their employment by other organizations outside of the Hartford HealthCare , and from which the individuals had duties that involved exposure to radiation.

3.8.3. Handling of Unanticipated Radioactive Waste (AV3-6)

The licensee's RSC meeting minutes described "Area Radiation Detectors" and "low level alarms" with some regularity. The inspectors noted a total of 27 alarms documented in the RSC's meeting minutes in calendar year 2022. The HOCC staff and representatives described these alarms as related to radiation portal monitors installed at two points in the main facility's exits for general trash services. While some of the minutes described this as the result of "in-patient waste" (meeting minutes for 2022 Quarter 1) and "in-house Tc-99m waste" (meeting minutes for 2022 Quarter 2), it did not appear that HOCC had exerted any material effort to investigate and identify the source of this apparently radioactive waste, and therefore conclude with any certainty or speculation on its origins.

The inspectors interviewed the manager of the Environmental Services group, who described the procedures and training for handling these alarms and provided a walk-down of a storage area and the two radiation portal monitors. The manager explained that waste which triggered the radiation portal monitors would be partitioned to identify the bag or container causing the alarm and that this bag or container would be segregated into a separate room for radioactive decay for three days before being passed through the radiation portal monitor again. If the portal monitor did not alarm, the waste would be deemed non-radioactive and continue to be handled through the normal non-radioactive waste processes. If the portal monitor alarmed for this post-decay check, Environmental Services would contact the Nuclear Medicine Department for assistance.

As the source of the waste was not identified and no further material efforts were exerted to identify the isotope of concern, HOCC could not conclude what the potential hazard was posed by the waste. Furthermore, HOCC could not state whether their existing controls for handling and processing known radioactive waste were experiencing failures or if this unanticipated waste resulted from other uncontrolled areas (for example, from patients in the Emergency Department who had radioactive administrations prior to their emergency, whether this administration had occurred at HOCC or another licensed facility). This, in part, contributed to deficiencies in addressing NRC regulatory

requirements, license limitations and commitments, and applicable HOCC policies and procedures.

While it is likely that the subject radioactive material was from or related to nuclear medicine operations, and thus represents short-lived, low-activity radionuclides, and therefore relatively limited hazards, HOCC had not demonstrated this to be the case.

These deficiencies can be further subdivided into four areas of concern: (1) decay-in-storage and monitoring; (2) decay-in-storage records; (3) confinement of possession and use of byproduct material to locations authorized by the NRC license; and (4) training for staff (10 CFR 35.92(a), 10 CFR 35.92(b) & 35.2092, 10 CFR 30.34(c), and License Condition 15(A), respectively). These items are described, in brief, below, along with the associated apparent violation.

First, the licensee's apparent failure to identify the isotopes of concern resulted in its inability to demonstrate that it was authorized to use the decay-in-storage provision provided in 10 CFR 35.92, as this authorization is contingent upon the byproduct material having a physical half-life of less than or equal to 120 days. In addition, the licensee's use of the radiation portal monitors failed to meet the regulatory requirement for monitoring the byproduct material that is being released via decay-in-storage, as it failed to monitor the byproduct material at its surface with an appropriate instrument at its most sensitive scale with no interposed shielding.

As a result of the above, an apparent violation of 10 CFR 35.92(a) was identified and is described below (030-01250/2023-001-03):

> *Apparent Violation No. 3: Decay-in-Storage Half-Life Limitation and Monitoring*
>
> 10 CFR 35.92(a) states, 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 the licensee monitors the 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, in numerous instances from at least March 24, 2021, through March 6, 2023, the licensee: (1) failed to ensure that byproduct material had a physical half-life of less than or equal to 120 days, prior to that byproduct material being decayed-in-storage; and (2) failed to monitor the byproduct material at the surface before disposal and determine that its radioactivity could not 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 unknown radioactive isotopes via decay-in-storage before releasing them as non-radioactive waste, and that disposal occurred without monitoring using an adequate instrument at the surface of the material.

Second, the licensee generated only auxiliary notes associated with the disposal of this unanticipated radioactive material, such as the notes in the RSC meeting minutes. The licensee attempted to identify and produce more detailed information such as the times

and occasions, or personnel involved, with individual disposals, and was not able to produce such records.

As a result of the above, an apparent violation of 10 CFR 35.92(b) and its associated requirement in 10 CFR 35.2092 was identified and is described below (030-01250/2023-001-04):

Apparent Violation No. 4: Decay-in-Storage Record Creation and Retention

10 CFR 35.92(b) requires that the licensee retain a record of each disposal permitted under 10 CFR 35.92(a) in accordance with 10 CFR 35.2092.

10 CFR 35.2092 requires that the licensee shall maintain records of the disposal of licensed materials, as required by 10 CFR 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

Contrary to the above, in numerous instances from at least March 24, 2021, through March 6, 2023, the licensee failed to create and retain a record of each disposal permitted under 10 CFR 35.92(a). Specifically, the licensee disposed of unknown radioactive isotopes and failed to create or retain a record regarding that disposal, including the specific items described in 10 CFR 35.2092.

Third, the licensee's retention of the unanticipated radioactive material involved temporary storage for the three-day period following initial identification in a secure room near the Environmental Services operations. This room was not identified by the licensee to the NRC in its most recent license application or subsequent communications amending the NRC license. The licensee's applications and subsequent communications include descriptions, consistent with NUREG-1556, Volume 9, Section 8.9 "Facilities and Equipment," of areas where byproduct material is prepared, used, administered, and stored.

As a result of the above, an apparent violation of 10 CFR 30.34(c) was identified and is described below (030-01250/2023-001-05):

Apparent Violation No. 5: Confinement of Byproduct Material to Authorized Locations

10 CFR 30.34(c) requires, in part, that each licensee shall confine its possession and use of byproduct material to the locations authorized in the license.

License Condition 15 of NRC License No. 06-02388-01, Amendment No. 123, dated February 7, 2023, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated August 18, 2022, and subsequent letters dated November 22, 2022, and January 19, 2023, including any enclosures.

The application dated August 18, 2022, and subsequent letters dated November 22, 2022, and January 19, 2023, identify and describe the locations where radioactive materials will be stored.

Contrary to the above, in numerous instances from at least February 7, 2023[3], through March 6, 2023, the licensee failed to confine its possession and use of byproduct material to the locations authorized in the license. Specifically, the licensee stored radioactive materials in a room not identified in the license application or subsequent letters by the licensee as a location of storage.

Fourth, and finally, the personnel of the Environmental Services Department were provided cursory hazard awareness training, consistent with all auxiliary staff at HOCC. While this would be sufficient to address the limited potential these staff normally have to encounter or be in proximity to radioactive materials, this training did not address subjects consistent with the handling of radioactive waste, such as the performance of adequate radiation surveys, contamination control, emergency procedures, record creation and retention, or other HOCC policies, procedures, and NRC regulations as they concern the handling and disposal of radioactive waste.

As a result of the above, an apparent violation of License Condition 15.A was identified and is described below (030-01250/2023-001-06):

Apparent Violation No. 6: Adequacy of Training

License Condition 15 of NRC License No. 06-02388-01, Amendment No. 123, dated February 7, 2023, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, in the letter dated November 22, 2022.

The application dated November 22, 2022, requires, in part, that the Hospital of Central Connecticut shall develop and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.

Contrary to the above, from February 7, 2023[3], through March 6, 2023, the licensee failed to develop and implement and maintain written procedures for a program for training. Specifically, auxiliary staff in the Environmental Services Department were assessing and disposing of unknown radioactive isotopes and the licensee failed to provide commensurate training to handle, assess, survey, and dispose of this radioactive waste properly.

[3] NRC License No. 06-02388-01 was renewed with Amendment No. 123, which was finalized and issued on February 7, 2023, and as a result included a new application to the NRC from HOCC consistent with NUREG-1556, Volume 9, Revision 3. The license prior to Amendment No. 123, and thus prior to February 7, 2023, included equivalent and commensurate commitments and descriptions. Therefore, while the apparent violation is quoted as beginning on February 7, 2023, this is for simplicity of communication, rather than an actual description of the licensee's apparent deficiency, which preceded the quoted date.

3.8.4. Additional Observation Regarding Unanticipated Radioactive Waste

The licensee committed in its November 22, 2022, application to the NRC to develop, implement, and maintain written waste disposal procedures for radioactive material in accordance with 10 CFR 20.1101, which also meets the requirements of the applicable section in 10 CFR Part 20, Subpart K, and 10 CFR 35.92. An equivalent and consistent commitment was made with the license prior to the renewal of the license[3]. While the inspectors noted several apparent gaps between the licensee's practices as described throughout Section 3.8.3 of this report with regards to the disposal of this unanticipated radioactive material and HOCC's written policy, the specific items were determined to be sufficiently addressed by AV3-6 above and therefore would be duplicative to include as a separate AV. As a matter of completeness and communication, a brief description is of this additional observation is provided below.

The licensee's responsive waste disposal procedure (titled "Radioactive Waste Management Plan" Revision August 2018, Manual Code 03.0005), required, in part, that:

- Section II "General Information:" "*All persons required to handle radioactive wastes will be provided with appropriate orientation, equipment, and on-the-job training*;" and "*Only the Nuclear Medicine Department and the Radiation Oncology Department are authorized by the Nuclear Regulatory Commission to possess radioactive material*;"
- Section IV "Storage of Waste Material:" "*All radioactive waste material will be stored in the designed shielded enclosures*" and "*Environmental Services employees will follow departmental policies for responding to the radiation alarm*;" and
- Section IV [sic] "Records for Disposal:" "*Records of disposal will include the following information: (1) the date placed in storage for decay and the container identification if applicable; (2) approximate total activity and volume (or number of sources for capsules, seeds, columns, etc.) at the time placed in storage; and (3) date disposed as regular trash and the survey meter reading*."

As AV4 and 6 already address apparent deficiencies in record generation and retention as well as the training provided to staff in the Environmental Services Department, these apparent gaps are already captured and described in the subject AVs. Regarding the second bullet noted above ("Storage of Waste Material"), the inspectors found that the segregated waste was not provided any designed shielded enclosure, and would instead be stored, absent any additional shielding, in the secured room near the Environmental Services Department. As the licensee did not know the isotope or quantity of material, it is unclear what hazard this posed to staff working in or around this room.

HOCC provided the NRC copies of its draft revisions to relevant policies and procedures, specifically the documents titled "NRC Regulated Radioactive Waste Disposal," "Radioactive Waste Management Plan," and "Radiation Portal Monitor Alarm." HOCC emphasized, however, that these were yet under draft and final decisions on long-term corrective actions were still being discussed and under review.

3.9. Conclusions

As a result of the NRC's inspection efforts, six apparent violations of NRC requirements were identified. These apparent violations included the failures to: (1) monitor occupational exposure of an interventional radiologist; (2) assess occupational dose to twelve staff who had occupational duties outside of the HOCC that involved exposure to radiation; (3) ensure that byproduct material being decayed-in-storage had a physical half-life of less than 120 days and perform adequate monitoring of the byproduct material prior to disposal; (4) create and retain a record of each disposal of byproduct material via decay-in-storage; (5) confine the possession and use of byproduct material to the locations authorized in the license; and (6) provide commensurate training to staff involved in the disposal of byproduct material via decay-in-storage.

4. Corrective Actions

With regards to AV1 concerning the apparent failure to monitor the occupational exposure of an interventional radiologist, the licensee's efforts to reconstruct the apparent gap in the occupational exposure records are documented in Section 3.8.1 above. The licensee had not yet communicated its actions, planned or completed, to address the consistent and accurate monitoring of occupational exposure in the future to ensure durable and lasting compliance with the associated regulatory requirement.

Similarly, for AV2 concerning the apparent failure to assess occupational dose to staff who had occupational duties outside of the HOCC that involved exposure to radiation, the licensee's actions to address prior occupational exposure at outside facilities is described in Section 3.8.2. The licensee has not yet communicated its actions, planned or completed, for how it intends to address this in the future to ensure durable and lasting compliance with the associated regulatory requirement.

Finally, for AV3-6, the licensee has taken steps to review and begin revision for relevant policies and procedures related to the handling of radioactive waste. Draft versions of these documents were shared with the NRC. However, HOCC has not yet communicated its final decision in how it intends to handle further radioactive waste identified outside its normal processes, which includes whether the current practice of handling this material principally by the Environmental Services Department will continue or not.

5. Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on March 7 and 8, 2023. The licensee acknowledged the findings presented and committed to formulating a corrective action plan. The NRC conducted a final exit briefing via teleconference on June 28, 2023. HOCC was represented by: Janette Edwards, MPH, MBA, Vice President of Operations; Gregory Hisel, Consultant and Radiation Safety Officer; George Pavlonnis, Associated Radiation Safety Officer; and other health physics and corporate support staff. The licensee again acknowledged the findings presented and did not dispute any of the facts presented.

SUPPLEMENTAL INSPECTION INFORMATION

LIST OF PERSONS CONTACTED

Janette Edwards, MPH, MBA, Vice President of Operations
Greggory Hisel, Consultant and Radiation Safety Officer
George Pavlonnis, Associate Radiation Safety Officer
Daniel Chiappetta, Radiation Safety Physicist

INSPECTION PROCEDURES USED

87130, Revision 1 – Nuclear Medicine Programs
87132 – Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED - PUBLIC

Opened

030-01250/2023-001-01	AV	Apparent failure to monitor occupational exposure of an interventional radiologist.
030-01250/2023-001-02	AV	Apparent failure to assess occupational dose to staff who had occupational duties outside of HOCC that involved exposure to radiation.
030-01250/2023-001-03	AV	Apparent failure to ensure that byproduct material being decayed-in-storage had a physical half-life of less than 120 days and the apparent failure to perform adequate monitoring of the byproduct material prior to disposal.
030-01250/2023-001-04	AV	Apparent failure to create and retain a record of each disposal of byproduct material via decay-in-storage.
030-01250/2023-001-05	AV	Apparent failure to confine the possession and use of byproduct material to the locations authorized in the license.
030-01250/2023-001-06	AV	Apparent failure to provide commensurate training to staff involved in the disposal of byproduct material via decay-in-storage.

(Continued on next page)

Closed

All violations associated with IR2021-001 are considered closed. The licensee no longer possesses, plans to possess, or is authorized to possess quantities of radioactive materials within the scope of 10 CFR Part 37.

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
ARSO	Associate Radiation Safety Officer
AU	Authorized User
AV	Apparent Violation
CFR	*Code of Federal Regulations*
CY	Calendar Year
HDR	High Dose Rate Afterloader
HOCC	The Hospital of Central Connecticut
ICR	Institute on Conflict Resolution
IR	Inspection Report
NMT	Nuclear Medicine Technologist
NRC	Nuclear Regulatory Commission
PEC	Pre-Decisional Enforcement Conference
PET/CT	Positron Emission Tomography / Computed Tomography
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer