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

August 8, 2022

EA- 22-048

John Rossi,
Vice President of System
and Fairfield Region Operations
Hartford Healthcare
St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

SUBJECT: ST. VINCENT'S MEDICAL CENTER - NRC INSPECTION REPORT 03001245/2022001

Dear Mr. Rossi:

This letter refers to a routine inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on March 2 and 3, 2022, with continued in-office review through July 12, 2022, of St. Vincent's Medical Center (St. Vincent's). The purpose of this inspection includes, a routine inspection of your activities performed under your NRC License No. 06-00843-03, and the follow-up on the improper disposal of a sealed source. The inspectors discussed the inspection findings with you, telephonically, on April 28, 2022, and during the final exit meeting on July 12, 2022.

This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examinations of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC identified 12 apparent violations that are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Three of the apparent violations are related to the failure to maintain control over a sealed source when, on October 22, 2021, a St. Vincent's contract employee inadvertently disposed of a sealed cesium-137 source as biohazard waste. The NRC notes that St. Vincent's staff retrieved the source on December 2, 2021. The apparent violations related to this event include the failure to: (1) dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2001(a); (2) monitor the surface of by-product material prior to disposal as decay-in-storage waste, as required by 10 CFR 35.92(a)(1); and (3) conduct a semi-annual physical inventory of sealed sources in your possession, as required by 10 CFR 35.67(g).

Additional apparent violations are related to the failure to maintain an effective radiation safety program and the failure to implement an adequate radiation exposure monitoring program. These apparent violations include the failure to: (4) include an authorized user on the Radiation Safety Committee for each type of use of byproduct material permitted by the license, as required by 10 CFR 35.24(f); (5) review periodically (at least annually) the radiation protection program content and implementation, as required by 10 CFR 20.1101(c); (6) implement procedures for the safe use of unsealed byproduct material, for which the licensee's procedure to ensure radiation exposure is as low as reasonably achievable (ALARA) required a formal annual review of the radiation safety program including ALARA considerations, pursuant to Condition 14 of License No. 06-00843-03 and the application submitted on September 30, 2013; (7) reduce the dose that an individual may be allowed to receive in the current year by the amount received while employed by any other person, as required by 10 CFR 20.1201(f); (8) implement procedures for the safe use of unsealed byproduct material, for which the licensee's ALARA procedure states the Radiation Safety Committee will consider exposures exceeding ALARA Level I in comparison with exposures of others performing similar tasks and record the review in the Radiation Safety Committee minutes and will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding ALARA Level II and, if warranted, take action, pursuant to Condition 14 of License No. 06-00843-03 and the application submitted on September 30, 2013; (9) control the occupational dose to individual adults to the annual dose limits, as required by 10 CFR 20.1201(a); (10) control release of a Yttrium-90 (Y-90) microsphere patient without determining that members of the public would not be exposed in excess of 5 mSv total effective dose equivalent (TEDE), as required by 10 CFR 35.75(a); (11) test sealed sources for leakage at intervals not to exceed 6 months, as required by 10 CFR 35.67(b)(2); and (12) conduct your program in accordance with the letter dated February 20, 2014 (ML14083A283), which requires you to include the treatment site on the written directive, pursuant to Condition 14 of License No. 06-00843-03.

The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you during the telephone call on April 28, 2022, and the inspection exit meeting on July 12, 2022. Since apparent violations involved the improper disposal of licensed material, the NRC is considering proposing imposition of civil monetary penalty. Section 2.3.4, Civil Penalty, of the Enforcement Policy states that for violations where a licensee has lost required control of its regulated licensed material for any period of time, the NRC normally will impose at least a base civil penalty. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

Before the NRC makes its enforcement decision, we are providing you an opportunity to discuss the apparent violations addressed in this inspection report at a Pre-decisional Enforcement Conference (PEC). This conference will be open to public observation in accordance with Section 2.4, Participation in the Enforcement Process, of the NRC Enforcement Policy. 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. Rather, due to the complex nature and significant number of apparent violations, a PEC is warranted to obtain information to assist the NRC in making an enforcement decision. Topics discussed during the PEC may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC

should take into consideration in making an enforcement decision. 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. Please note that if a PEC is held, the NRC would issue a press release to announce the conference time and date. Following the PEC, you will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations, other than to arrange the PEC, is required at this time.

The PEC should be held within 30 days of the date of this letter. Please contact Ms. Anne DeFrancisco at anne.defrancisco@nrc.gov within **10 days** of the date of this letter to schedule the PEC. If you do not contact the NRC within the time specified, and an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

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

Sincerely,

Blake D. Welling Digitally signed by Blake D. Welling
Date: 2022.08.08 20:48:18 -04'00'

Blake D. Welling, Director
Division of Radiological Safety and Security
Region I

Docket No. 030-01245
License No. 06-00843-03

Enclosure:
Inspection Report w/Attachment (Apparent Violations)

cc w/Encl: Greg Hisel, CHP, Radiation Safety Officer
State Connecticut

ST. VINCENT'S MEDICAL CENTER - NRC INSPECTION REPORT
03001245/2022001 DATED AUGUST 8, 2022

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001245/2022001
Docket No.	03001245
License No.	06-00843-03
EA No.	EA-22-048
Licensee:	St. Vincent's Medical Center Dba Hartford HealthCare Medical Group
Address:	2800 Main Street Bridgeport, CT 06606 2979 Main Street Bridgeport, CT 06606
Inspection Dates:	March 2-3, 2022, April 28, 2022, and in office review through July 12, 2022
Exit Meeting	July 12, 2022

Inspector: Anne DeFrancisco for Robin Elliott — August 8, 2022 (date)
Robin Elliott
Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Inspector: Hiba Ahmed — August 8, 2022 (date)
Hiba Ahmed
Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By: Anne DeFrancisco — August 8, 2022 (date)
Anne DeFrancisco
Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

EXECUTIVE SUMMARY

St. Vincent's Medical Center
Dba Hartford HealthCare Medical Group
NRC Inspection Report No. 03001245/2022001

On March 2 and March 3, 2022, a special routine announced inspection was initiated at St. Vincent's Medical Center dba Hartford HealthCare Medical Group (St. Vincent's) regarding U.S. Nuclear Regulatory Commission (NRC) radioactive materials license number 06-00843-03. In office review continued through July 12, 2022, when an exit meeting was held with licensee management and staff.

The purpose of the inspection was to follow-up on an unreported improper disposal of a cesium-137 (Cs-137) sealed source from October 2021 and to review any corrective and preventative actions. Additionally, a routine inspection was performed under inspection procedures 87131 and 87132. The inspectors conducted risk-informed and performance-based interviews with licensee staff, observed a variety of licensee activities and conducted a thorough review of select records. The inspectors also followed up on two violations from the previous inspection held in April 2021.

Based on the results of this inspection, the NRC identified 12 apparent violations that are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Three of these apparent violations are related to the failure to maintain control over a sealed source when, on October 22, 2021, a St. Vincent's contract employee inadvertently disposed of a sealed Cs-137 source as biohazard waste. The NRC notes that St. Vincent's staff retrieved the source on December 2, 2021. The apparent violations related to this event include the failure to: (1) dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2001(a); (2) monitor the surface of by-product material prior to disposal as decay-in-storage waste, as required by 10 CFR 35.92(a)(1); (3) conduct a semi-annual physical inventory of sealed sources in your possession, as required by 10 CFR 35.67(g).

Additional apparent violations are related to the failure to maintain an effective radiation safety program and the failure to implement an adequate radiation exposure monitoring program. These apparent violations include the failure to: (4) include an authorized user on the Radiation Safety Committee for each type of byproduct material permitted by the license, as required by 10 CFR 35.24(f); (5) review periodically (at least annually) the radiation protection program content and implementation, as required by 10 CFR 20.1101(c); (6) implement procedures for the safe use of unsealed byproduct material, for which the licensee's procedure to ensure radiation exposure is as low as reasonably achievable (ALARA) required a formal annual review of the radiation safety program including ALARA considerations, pursuant to Condition 14 of License No. 06-00843-03 and the application submitted on September 30, 2013; (7) reduce the dose that an individual may be allowed to receive in the current year by the amount received while employed by any other person, as required by 10 CFR 20.1201(f); (8) implement procedures for the safe use of unsealed byproduct material, for which the licensee's ALARA procedure states the Radiation Safety committee will consider exposures exceeding ALARA Level I in comparison with exposures of others performing similar tasks and record the review in the Radiation Safety Committee minutes and will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding ALARA Level II and, if warranted, take action,

pursuant to Condition 14 of License No. 06-00843-03 and the application submitted on September 30, 2013; (9) control the occupational dose to individual adults to the annual dose limits, as required by 10 CFR 20.1201(a); (10) control release of a Yttrium-90 (Y-90) microsphere patient without determining that members of the public would not be exposed in excess of 5 mSv total effective dose equivalent (TEDE), as required by 10 CFR 35.75(a); (11) test sealed sources for leakage at intervals not to exceed 6 months; as required by 10 CFR 35.67(b)(2); and (12) conduct your program in accordance with the letter dated February 20, 2014, which requires you to include the treatment site on the written directive, pursuant to Condition 14 of License No. 06-00843-03 (this is a repeat violation).

REPORT DETAILS

1.0 Inspection and Program Scope

1.1 Inspection Scope

On March 2-3, 2022, the NRC conducted an announced routine inspection of St. Vincent's. The on-site inspection was conducted at St. Vincent's facilities located in Bridgeport, Connecticut. The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC rules, NRC regulations, and conditions of the license. Additionally, the inspection was to investigate the circumstance surrounding the loss of licensed material reported to the NRC involving a 114 uCi sealed source of Cs-137 originating from St. Vincent's and recovered at the biohazardous waste vendor's Woonsocket facility in Rhode Island.

In office review continued through July 12, 2022. The inspection activities were performed in accordance with NRC Inspection Procedures (IP) 87131 and 87132. Throughout the inspection, inspectors conducted interviews with the licensee's personnel, observed operations, toured facilities, and reviewed selected records and documents.

1.2 Program Scope

At the time of the inspection, St. Vincent's operated one hospital and four satellite facilities under NRC License Number 06-00843-03. The license authorized the use of byproduct material permitted by 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.600 (HDR), and Yttrium-90 (Y-90) microspheres under 10 CFR 35.1000. The hospital had nuclear medicine (NM) and PET/CT departments as well as a Radiation Oncology department. The NM department was responsible for routine nuclear medicine procedures as well as various radiotherapy programs involving the administration of Iodine-131, Radium-223, and Y-90. The Radiation Oncology department had established an HDR program. St. Vincent's had a Heart and Vascular Center authorized for activities under 10 CFR 35.200 and three off-site clinics that performed a variety of activities under 10 CFR 35.100 and 10 CFR 35.200.

1.3 Management Oversight

St. Vincent's became part of the Hartford Healthcare Corporation in October of 2019. As part of this system of healthcare providers, the licensee received access to a corporate Radiation Safety Officer (RSO). A Radiation Safety Committee provided program oversight and met quarterly. The licensee has experienced turnover in their RSO position, changing consultant RSOs in January of 2019 (when the committed time to provide oversight was designated as 2-3 hours per week but also included supervising a junior physicist and technologist), October of 2020 (when the committed time to provide oversight was designated as 16 hours per month) and then again in May of 2022 (when the committed time to provide oversight was designated as 32 hours per month). However, the current RSO was added as an Associate RSO with the previous RSO change in October of 2020, that provided better continuity than with the previous change. The RSO was supported by the Radiology Manager and the Director of Radiology.

2.0 Routine Inspection

2.1 Inspection Scope

The inspectors performed an announced routine inspection utilizing NRC Inspection Procedure 87131, “Nuclear Medicine Programs, Written Directive Required”, to conduct the inspection. Information was gathered through interviews with cognizant personnel, direct observation of licensed activities, review of records, tours of the facilities, and through the performance of independent radiation surveys. Specifically, the procedures and use of brachytherapy and nuclear medicine therapies requiring written directives were reviewed in an attempt to close out the previous violations related to the Y-90 microsphere program.

2.2 Direct Observations, Interviews, and Records Review

The inspectors toured the general nuclear medicine and PET/CT departments at 2800 Main Street and Cardiology departments at the 2800 Main Street and 2979 Main Street in Bridgeport, Connecticut. The inspectors interviewed three nuclear medicine technologists while touring and observing daily activities. The inspectors discussed the radiopharmacy security access, waste disposal and observed quality control of daily use instruments such as well-counters, dose calibrators and survey meters. The licensee’s staff demonstrated safe nuclear medicine and radiation protection practices. The inspectors observed HDR spot check procedures as well as a gynecological HDR Treatment. It was noted that the authorized user and authorized medical physicist were present for the entire duration of the HDR treatment. Radiation alarms and radiation protection measures were adequately in place.

2.3 Observations and Findings

2.3.1 Y-90 Microsphere Written Directives

The licensee was cited in their April 13-14, 2021, inspection, for violations of 10 CFR 35.41(a) and (b) and License Condition 14 which requires them to comply with commitments made in their letter dated February 20, 2014, with respect to their Y-90 microsphere program. Specifically, the licensee’s written procedure did not specify that the target organ would be recorded on the written directive, did not specify the dose calculation method other than the manufacturer’s, and did not evaluate the effect of patient weight discrepancies. A re-evaluation of these items for the patient treated on May 13, 2021, after the on-site April 13-14, 2021, inspection did not reflect correction of these items. The procedure had not been updated (date on the procedure was February 2020) and the target organ was not indicated on the form. This was discussed with the physician who indicated that the dose calculation method was revised; however, the form used to document the treatment had not been updated to include the target organ until after the completion of the 2021 inspection in July of 2021.

2.3.2 Sealed Source Leak Testing

The licensee utilized a 100 uCi Ge-68 pin source which was internally mounted in a PET camera for calibration. The licensee stated that the leak testing of this source was only performed when the manufacturer came for routine maintenance. The source was not leak tested between April 2021 and March 2, 2022, violating the requirements of 10 CFR 35.67 (b) (2) requiring source leak testing at intervals not to exceed 6 months.

The licensee was informed that the sealed sources could be tested without direct access to them by wiping the most accessible area where contamination would most likely be found. The licensee performed the required leak test on March 21, 2022 and committed to not waiting for the manufacturer's test but performing the tests on the required six-month basis going forward.

2.3.3 Radiation Safety Committee

As part of the radiation protection program to oversee licensed activities, St. Vincent's is required to establish a Radiation Safety Committee (RSC) to provide oversight of the radiation protection program because they are authorized for two or more different types of uses of byproduct material under 10 CFR Part 35 Subparts E, F, and H. The RSC did not have the membership required by 10 CFR 35.24(f) because it did not have an Authorized User (AU) appointed to address 10 CFR 35.1000 Y-90 microsphere uses. Additionally, the AU representing 10 CFR 35.100-300 uses was not present at a meeting since January 18, 2021. The inspectors also noted that the committee did not have representation from each of the satellite locations. While this is not dictated by regulation, the inspectors noted differences in Nuclear Medicine (NM) procedures by location which may have been addressed by the committee if it had such broader representation.

2.3.4 Radiation Protection

The Radiation Protection program was not providing adequate oversight of the uses of licensed material. Inspectors noted that the licensee has utilized three different consultant Radiation Safety Officers (RSO) over the past three years. Given the size of the program, it is difficult for an individual to make progress on program management without continuity. It is thought that these changes in personnel may have resulted in a failure to maintain proper oversight of the radiation protection program as evidenced by the following failures:

- The licensee was required by 10 CFR 20.1101(c) and their internal ALARA policy 35.20, to perform a formal review of the Radiation Safety Program to include the ALARA program annually. The licensee had not conducted a review to meet either requirement between April 2021 and March 2022 and for an undetermined amount of time prior. These reviews should have been presented to the RSC for review and discussion.
- The licensee's ALARA program, which the licensee reviewed and revised as recently as April 2020, addressed many aspects of the radiation monitoring program such as conducting the annual ALARA program review and quarterly exposure reviews.
    - Investigational Levels were established for ALARA I and ALARA II levels which required follow-up by the RSO and discussion at the RSC meetings. The review of documentation found that while individuals were notified of their exceedance of the ALARA I or ALARA II levels, follow up by the RSO was not being done and nothing was presented to the RSC.
    - With regard to the monitoring program in general, it was also noted that there was no follow-up performed with regard to missing or unused dosimeters, as reported to the RSC, resulting in incomplete radiation exposure records contrary to 10 CFR 20.1201(a). Calculations for adjusted dose were not made for late or missing badges to update employee yearly dose records.

- Additionally, contrary to 10 CFR 20.1202(a), the inspectors learned that not all radiation workers, who were likely to exceed 10 percent of the occupational exposure limits, were being monitored by St. Vincent's. Specifically, two of the three contract physicians authorized for Y-90 microsphere use did not have dosimeters issued by St. Vincent's. They were issued dosimeters through their employer, Advanced Radiology Contractors. A review of their 2021 exposures revealed they had no recorded exposure, an unlikely result for interventional radiologists (IR). Although, it was observed that one IR physician was wearing a dosimeter on March 3, 2022, during the inspection. Therefore, the IR physicians' exposure was not being reviewed by St. Vincent's.
- Likewise, St. Vincent's failed to maintain cumulative occupational exposure for employees being monitored by another employer. Employees working for other employers, such as the IR physicians, were not having their exposure from their other employers factored into their exposure at St. Vincent's contrary to 10 CFR 20.1201(f).

2.3.5 Therapy Patient Release Calculations

The inspectors reviewed the written procedures for Y-90 microsphere therapies, Ra-223 Xofigo therapies, Iodine-131 therapies, and Y-90 Zevalin therapies. It was noted that the basis for the release of the patients was only addressed for the Iodine-131 patients. Only one therapy for Y-90 microspheres was conducted during the inspection period and there was no release calculation performed to document the basis of the patient's release under 10 CFR 35.75. The licensee provided a calculation on June 17, 2022, to demonstrate that the patient was releasable in accordance with 10 CFR 35.75. The licensee was advised to document the basis for patient release for all therapies going forward.

2.3.6 Manual Brachytherapy

At the time of the inspection, the license listed authorized activities under 35.400 but reported that no procedures had been performed in approximately ten years. It was also unknown whether the AUs had maintained any continuing education for these activities. The licensee submitted an amendment request on May 17, 2022, to remove this authorization.

3.0 Investigation of Loss of Control of Sealed Source at 2979 Main Street Location

3.1 Summary of event

The licensee lost control of a 114 uCi Cs-137 sealed source on or about October 22, 2021, until December 2, 2021. The source was transferred to 2979 Main Street in Bridgeport, Connecticut when its facility in Hamden, Connecticut was decommissioned. Following the source's transfer, it was stored in a lead lined radioactive waste container in the hot lab appropriately labelled for waste. It was not added to the sealed source inventory list at the time it arrived at the 2979 Main Street location. There was typically only one Nuclear Medicine Technologist (NMT) working at the 2979 Main Street location who was aware of the presence of the source. On October 22, 2021, a temporary "per diem" NMT was working at the location. This individual was using that radioactive waste can for waste generated that day. At the end of the day the NMT disposed of the contents of the can into the biohazardous waste without performing a survey of the

waste. The per diem NMT was unaware of the presence of the radioactive source, which was disposed of in the biohazardous waste. The biohazardous waste was taken by the biohazardous waste vendor to their Woonsocket, Rhode Island facility where the source was detected by setting off radiation monitors. On October 27, 2021, the biohazardous waste vendor notified St. Vincent's that they had received waste containing radioactive material from their facility. From November 16 through November 23, 2021, the licensee worked with the biohazardous waste vendor on how to retrieve the source and obtained documentation of its origin. The biohazardous waste vendor's facility stored the source until St. Vincent's arranged for the source's return on December 2, 2021.

3.2 Licensee's response

The licensee conducted a root cause analysis of the incident and found that the failure was a result of the per diem employee not following required protocols. The per diem employee was no longer working with the licensee at the time of the inspection and was unavailable for an interview. The licensee implemented several corrective actions: the source was returned to the waste container but a larger "DO NOT REMOVE" sign was placed on can. With regard to future biohazardous waste collections – trash is surveyed a second time to confirm it is at background radiation levels and the lead can containing the sources is inventoried to confirm that all radioactive sources remain at St. Vincent before the biohazardous waste vendor removes the waste. Additionally, the licensee pursued the return of the sources to the manufacturer for their disposal.

3.3 Findings

Upon investigation of the above incident, the inspectors determined that the sources obtained from the decommissioned Hamden site were not added to the licensee's inventory of sealed sources until February 2022. As a result, they were not inventoried from September 2019 to February 2022 in violation of 10 CFR 35.67(g) which requires an inventory every six months. The licensee also violated 10 CFR 20.2001(a) and 10 CFR 35.92(a)(1) by disposing of the Cs-137 source in the biohazardous waste because (1) that disposal or transfer was to an unauthorized recipient and (2) the source was treated as decay-in-storage waste which is only permitted for material with a half-life of less than or equal to 120 days, and the half-life of Cs-137 exceeds 120 days. Because these violations are associated with a loss of licensed material, based on the NRC Enforcement Policy, they are being considered for escalated enforcement.

3.4 Corrective actions

It is noted that returning the sources to the same waste storage container that has already once been mistaken for containing decay-in-storage waste does not appear to be a satisfactory corrective action. However, survey requirements, and verification of the sealed source inventory prior to waste disposal will help to assure that a repeat inadvertent disposal does not occur. On June 7, 2022, the licensee disposed of the source, along with three other sources in storage, through a licensed radioactive waste broker for a cost of $4,073.

4.0 Independent Radiation Measurements

All licensee staff were found to utilize radiation dosimetry. Independent surveys were conducted of PET/CT hot lab, Cardiology hot lab at both sites as well as the HDR control and procedure rooms. The survey results were consistent with licensee postings, results, and within regulatory limits. No issues identified.

Instrument type: Model Ludlum 2401P
NRC S/N: 281068
Calibration expiration: 12/17/2022

5.0 Conclusions

During the inspection, overarching programmatic issues were noted which are thought to be the result of inadequate management oversight through the Radiation Safety Committee and the high turnover of Radiation Safety Officers from 2019 to the present. The change to Hartford Healthcare System may also be a factor in the lack of attention to the Radiation Safety Program. The result of the lack of oversight is evident by the observations captured in Section 2.3. Additionally, inconsistencies were found in the policies and procedures used across affiliate locations. Since the license includes multiple locations, the policies and procedures should be consistent across the various locations.

During this inspection, twelve apparent violations of NRC requirements were identified. The apparent violations are listed in the Attachment and are being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy.

6.0 Exit Meeting

On March 3, 2022, the inspectors conducted an onsite debrief exit meeting with the licensee and management. The initial inspection findings and apparent violation were discussed. The licensee acknowledged the inspection findings. On March 8, 2022, an email reiterating those findings was sent to the licensee to begin review and corrective actions. A follow-up email was sent to the licensee on June 15, 2022, summarizing the outstanding items that had not been addressed. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were again discussed with the licensee during a telephone call on April 28, 2022, with the final exit meeting being held July 12, 2022.

PARTIAL LIST OF PERSONS CONTACTED

#+^	John Rossi:	VP Operations
#+^	Gregory Hisel:	Temporary RSO
+	Kerianne Kraft:	Nuclear Medicine Technologist
+	Amy Cone Landan:	Nuclear Medicine Technologist
#+^	Patricia Burnes:	Director Quality Management
*^	Kelli Hannan:	Radiology Manager
*	Nicole Tommasino:	Radiation Therapist
*^	Aljallad Mohammed	Hartford Healthcare System RSO
*	Christopher Ianuzzi:	Radiation Oncologist
#*^	David Scagliarini:	Director of Cardiology
^	Curtis Mccloggan	Director of Radiology

Individual(s) present at entrance meeting on March 2, 2022
+ Individual(s) present for onsite inspection debrief on March 3, 2022
* Individual(s) present for virtual inspection debrief on March 3, 2022
^ Individual(s) present for exit meeting on July 12, 2022

INSPECTION PROCEDURES USED

IP 87131, Nuclear Medicine Programs, Written Directive Required
IP 87132, Brachytherapy Programs

LIST OF ACRONYMS USED

ALARA: As Low As Reasonably Achievable
AU: Authorized User
AMP: Authorized Medical Physicist
HDR: High Dose Rate Remote afterloader
NM: Nuclear Medicine
NMT: Nuclear Medicine Technologist
NRC: Nuclear Regulatory Commission
RSC: Radiation Safety Committee

ATTACHMENT

APPARENT VIOLATIONS:

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

Contrary to the above, from October 22, 2021, through December 2, 2021, the licensee failed to dispose of licensed material only by transfer to an authorized recipient, decay in storage, or by release in effluents within the limits of 10 CFR Part 20. Specifically, on October 22, 2021, the licensee inadvertently transferred a sealed source containing 114 microcuries of cesium-137 to an unauthorized recipient. The licensee retrieved the source on December 2, 2021.

B. 10 CFR 35.92(a)(1) requires, in part, that a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level.

Contrary to the above, on or about October 22, 2021, the licensee held byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity but did not monitor the byproduct material at the surface before disposal. Specifically, the licensee disposed of medical waste generated during the use of licensed material with a physical half-life of less than 120 days and did not survey the waste prior to disposal.

C. 10 CFR 35.67(g) requires, in part, that licensees in possession of sealed sources or brachytherapy sources shall conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a semi-annual physical inventory of all sealed sources in its possession. Specifically, the licensee moved three sealed sources from their Hamden, Connecticut office in September 2019 to the Heart and Vascular Center in Bridgeport, Connecticut but did not include the sources on the inventory until February 2022, and therefore did not conduct a semi-annual physical inventory from September 2019 to February 2022.

D. 10 CFR 35.24 (f) requires, in part, that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee (RSC) to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer.

Contrary to the above, the licensee was authorized for two or more different types of uses under Subparts E, and F and their RSC did not include an authorized user of

each type of use permitted by the license. Specifically, the license authorized 10 CFR 35.1000 Y-90 microsphere use and no authorized user representing this use was part of the RSC membership. Additionally, the license authorized 10 CFR 35.300 uses as well and the AU for 10 CFR 35.300 was not present at any of the RSC meetings held from January 18, 2021, to March 2, 2022.

E. 10 CFR 20.1101(c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, for more than one year prior to March 2, 2022, the licensee did not periodically (at least annually) review the radiation protection program content and implementation. Specifically, the licensee did not conduct an annual review of the radiation protection program from the last inspection, performed on April 13, 2021, and for an undetermined period of time prior to that.

F. License Condition 14 of License No. 06-00843-03 requires, in part, that the licensee conduct their program in accordance with the statements, representations, and procedures contained in the application dated September 30, 2013. The application dated September 30, 2013, requires the licensee to, in part, develop and implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

The licensee's ALARA program 35.20 dated February 4, 1981, states: "Management Commitment: We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc. and consultations with the radiation protection staff or outside consultants."

Contrary to the above, the licensee did not perform a formal annual review of the radiation safety program including ALARA considerations, nor did the licensee review the operating procedures and past exposure records, inspections, etc. Specifically, quarterly audits were performed of the Nuclear Medicine and Radiation Oncology departments; however, no formal annual review was performed for 2020 and for an undetermined period of time prior to 2020.

G. 10 CFR 20.1201(f) requires, in part, the licensee 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.

Contrary to the above, between April 13, 2021, and March 2, 2022, and for an undetermined period of time prior to that date, 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 had per diem employees and physicians (contract employees) that worked at other facilities where radiation exposure was received and did not have a program to capture their exposure record from other employers to reduce their allowable exposure at St. Vincent's.

H. License Condition 14 of License No. 06-00843-03 requires, in part, that the licensee conduct their program in accordance with the statements, representations, and procedures contained in the application dated September 30, 2013. The application dated September 30, 2013, requires the licensee to, in part, develop and implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

The licensee's ALARA program 35.20 dated February 4, 1981, in the section on the Establishment of Investigational Levels to Monitor Individual Occupational External Radiation Exposures, states the following:

- With respect to ALARA Level I investigations, "the Radiation Safety committee (RSC) will consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes;"

- With regard to ALARA Level II investigations: "The Radiation Safety Officer (RSO) will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action;" and

- Regarding the investigations, "the minutes, containing details of the investigation, will be made available for NRC inspectors for review at the time of the next inspection."

Contrary to the above, the licensee's RSC did not consider exposures exceeding ALARA Level I in comparison with exposures of others performing similar tasks as an index of ALARA program quality and record the review in the Committee minutes, and the RSO did not investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. Specifically, the minutes of the July 19, 2021, RSC meeting recorded that two individuals exceeded the ALARA I level and one individual exceeded the ALARA II level; however, there was no investigation recorded in the minutes and the inspector was informed that the individuals were simply informed of their exposure.

I. 10 CFR 20.1201(a) requires, in part, that licensees shall control the occupational dose to individual adults to the following dose limits: (1) An annual limit, which is the more limiting of (i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or (ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv). (2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are: (i) A lens dose equivalent of 15 rems (0.15 Sv), and (ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

Contrary to the above, between April 13, 2021, and March 2, 2022, the licensee did not control the occupational dose to individual adults to the annual dose limits referenced above. Specifically, the licensee did not add exposure from lost/not returned badges to the individuals exposure records to assure the exposure did not exceed the occupational limits. The RSC committee meeting minutes from January

2021, April 2021, July 2021, October 2021, and January 2022, report the number of late, unused and missing dosimeters; however, no action was taken to assure that the missing dose was reconstructed and added to the individuals' exposure records to verify that the occupational dose limits were not exceeded. Additionally, two physicians, who were determined to potentially exceed 10% of the occupational exposure limit and authorized to perform Y-90 microsphere therapies were not issued dosimetry to evaluate their occupational dose.

J. 10 CFR 35.75 (a) requires, in part, that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Contrary to the above, between April 13, 2021, and March 2, 2022, the licensee authorized the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material without determining if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). Specifically, a Y-90 therapy was performed on May 13, 2021, without performing release calculations to verify that the released patient would not pose an exposure risk to any other individual in excess of 5 mSv total effective dose equivalent.

K. 10 CFR 35.67 (b) (2) requires the license 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, as of April 2021, the licensee did not 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 possessed Ge-68 sealed sources greater than 100 uCi mounted in the PET camera which were not leak tested between April 2021 and March 2, 2022.

L. Condition 14 of NRC License No. 06-00843-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the letter dated February 20, 2014. The letter dated February 20, 2014, requires in part, that the licensee include the treatment site on the written directive.

Contrary to the above, on May 13, 2021, the licensee did not conduct its program in accordance with the procedures contained in the letter dated February 20, 2014. Specifically, the licensee performed a Y-90 microsphere treatment and did not indicate the target organ where the intended dose should be delivered.