UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

July 10, 2023

Cheryl Ficara, RN, MS
HHC Senior Vice President
Hartford Hospital
80 Seymour Street
Hartford, CT 06106

SUBJECT: HARTFORD HOSPITAL - NRC INSPECTION NO. 03001239/2023001 AND NOTICE OF VIOLATION

Dear Cheryl Ficara:

This letter refers to the inspection conducted on March 15 & 16, 2023 at your Hartford, Connecticut locations (Inspection Report No. 03001239/2023001, enclosed). 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 examination of procedures and representative records, observations of activities, and interviews with personnel. The enclosed report presents the results of this inspection. The inspection included in office review through May 2023 and the exit meeting held with Sandra Phillips, Director of Diagnostic Imaging, and other members your staff on June 29, 2023.

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

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report 03001239/2023001 and licensee correspondence dated March 27, 2023 (ML23087A235). Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC 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 regarding this matter, please contact Robin Elliott of my staff at 610-337-5076 or via electronic mail at Robin.Elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,

Anne E. DeFrancisco

Digitally signed by Anne E. DeFrancisco
Date: 2023.07.10 17:12:09 -04'00'

Anne E. DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-01239
License No. 06-00253-04

Enclosure(s):
1. Notice of Violation
2. Inspection Report No. 03001239/2023001

Cc: Jason Marsden, Radiation Safety Officer
State of Connecticut

HARTFORD HOSPITAL - NRC INSPECTION NO. 03001239/2023001 AND NOTICE OF VIOLATION DATED JULY 10, 2023

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DOCUMENT NAME: G:\WBL Documents\WBL Inspection Cover Letter\L06-00253-04.2023001.NOV.docx

X SUNSI Review		X Non-Sensitive ☐ Sensitive		X Publicly Available ☐ Non-Publicly Available	
OFFICE	R1: DRSS	R1: DRSS			
NAME	RElliott (rle)	ADeFrancisco (aed)			
DATE	July 5, 2023	July 7, 2023			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Hartford Hospital
Hartford, Connecticut

Docket No. 030-01239
License No. 06-00253-04

During an NRC inspection conducted on March 15-16, 2023, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. 10 CFR 35.610(e) requires, in part, that licensees shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

   Contrary to the above, for 2022, the licensee did not ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually. Specifically, one authorized user who was authorized for use of the high dose rate afterloader did not participate in the emergency training in 2022.

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

2. 10 CFR 35.40(b)(2) requires, in part, that written directives must contain the patient or human research subject's name and the following information for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration.

   Contrary to the above, from March 2021 until March 2023, the licensee's written directives did not contain the patient or human research subject's name and the following information for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration. Specifically, written directives for administrations of Lu-177, Lutathera® did not contain the route of administration.

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

3. 10 CFR 35.60(a) states, in part, for direct measurements performed in accordance with 10 CFR 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject. Furthermore, 10 CFR 35.60(b) states, in part, a licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

   Contrary to the above the licensee did not calibrate the instrument used to measure the activity of the dosage administered to each patient in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. Specifically, from March 2021 through March 2023, the licensee did not calibrate the dynamic detector used to measure the dosage of Rb-82 as part of their Rb-82 generator since neither nationally recognized standards nor the manufacturer's instructions exist for this type of detector. Further, at least one of the criteria in EGM 13-003 was not met. Specifically, the RSOs overseeing the program during the inspection period as well as the

Authorized User had not completed training specific to the generator.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

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

Dated This 10th day of July 2023

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001239/2023001
Docket No.	03001239
License No.	06-00253-04
Licensee:	Hartford Hospital
Address:	80 Seymour Street Hartford, CT 06106 282 Washington Street Hartford, CT 06106 Blue Back Square 65 Memorial Road, Building C, Suite 500 West Hartford, CT
Inspection Dates:	March 15-16, 2023, and in office review through June 29, 2023
Exit Meeting	June 29, 2023

Inspector: *Robin Elliott* June 27, 2023

Robin Elliott date
Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Inspector: *Hiba Ahmed* May 23, 2023

Hiba Ahmed date
Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By: *Anne DeFrancisco* June 27, 2023

Anne DeFrancisco date
Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

EXECUTIVE SUMMARY

Hartford Hospital
Report No. 03001239/2023001

On March 15 and March 16, 2023, a routine announced inspection was performed at Hartford Hospital (HH) regarding U.S. Nuclear Regulatory Commission (NRC) radioactive materials license number 06-00253-04. In office review continued through June 29, 2023, when an exit meeting was held with licensee management and staff.

The purpose of the inspection was to evaluate compliance with USNRC regulations by evaluating licensee activities, policies, and procedures in accordance with inspection procedures 87130, 87131, 87132, and Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance. The inspectors conducted risk-informed and performance-based interviews with licensee staff, toured licensed locations conducting radiation surveys, observed a variety of licensee activities and conducted a thorough review of select records.

During the inspection three Severity Level IV (SLIV) violations of NRC requirements were identified. The violations involved the failures to: 1) ensure that all authorized users of the high dose rate afterloader (HDR) received annual drills of the emergency procedures, 2) include the route of administration on Lutetium-177 (Lu-177) Lutathera® therapy written directives, and 3) calibrate the dynamic detector used to measure the dosage of Rb-82 as part of their Jubilant Rb-82 generator since neither nationally recognized standards nor the manufacturer's instructions exist for this type of detector and at least one of the criteria in Enforcement Guidance Memorandum (EGM) 13-003 was not met.

REPORT DETAILS

1.0 Inspection and Program Scope

1.1 Inspection Scope

The inspectors reviewed the organization and scope of the licensee's programs through direct observation of work activities, interviews with licensee workers, and review of selected records.

1.2 Program Scope

At the time of the inspection, Hartford Hospital operated one hospital and two satellite facilities under NRC License Number 06-00253-04. 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 35.500, Strontium-90 sealed sources for instrument calibration, 10 CFR 35.600 (HDR), and Y-90 microspheres under 10 CFR 35.1000. The hospital had nuclear medicine (NM), PET/CT, and Cardiology 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 Yttrium-90. The Radiation Oncology department performed prostate implants and eye plaques under 10 CFR 35.400. They also had an established HDR program as well as a dedicated location for therapy infusions utilizing Lu-177.

The license also authorized 10 CFR 35.100 – 10 CFR 35.400 activities at Connecticut Children's Medical Center (CCMC); however, it was concluded that 10 CFR 35.400 activities were no longer performed at this location and the licensee agreed to submit a request to remove this authorization.

The license authorized 10 CFR 35.100 and 200 activities at the Blue Back Square location. This area primarily performed lymphoscintigraphies using Tc-99m.

1.3 Management Oversight

Licensed activities at HH were managed by a Radiation Safety Committee that met quarterly and included representation as required by 10 CFR 35.24. The Radiation Safety Officer (RSO) also served as the corporate RSO for Hartford Healthcare, providing radiation safety support to other corporate sites. Since the last inspection in March of 2021, there have been three RSO changes. A long-term full-time RSO left HH in December 2021, and a new RSO was appointed. This RSO left in December of 2022, and a temporary RSO was appointed until a new consultant RSO was hired in February 2023. The newly appointed RSO committed to providing 20 hours a week in the RSO function. The RSO was supported by a staff of two diagnostic medical physicists, a Radiation Safety Physicist, and two Assistant Radiation Safety Officers.

Prior to February 2023, the RSO and Director of the HHC Radiation Protection Program reported to the Vice President of Quality and Safety. At the time of the inspection, the Radiation Protection staff had been moved under Director of Diagnostic Imaging who reported to the Senior Director of Clinical Operations (SDCO). The SDCO reported that one of the Assistant RSOs was being trained to serve as a back-up for the current RSO. HH was considering the feasibility of hiring the current consultant RSO full-time depending on the RSO's career plans. HH was evaluating the new structure to determine if it would remain the same going forward and was planning activities to

improve the overall radiation safety program.

2.0 Routine Inspection

2.1 Inspection Scope

The inspectors performed an announced routine inspection utilizing NRC Inspection Procedures 87130, “Nuclear Medicine Programs,” 87131, “Nuclear Medicine Programs, Written Directive Required,” and 87132, “Brachytherapy Programs.” 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.

2.2 Direct Observations, Interviews, and Records Review

The inspectors toured the general nuclear medicine, PET/CT, Cardiology and Radiation Oncology departments at 80 Seymour Street, Hartford and the NM facilities at 65 Memorial Road, West Hartford, CT. The inspectors also toured the CCMC where procedures limited to Iodine-131 therapies and NM brain ictal seizure studies were performed under 10 CFR 35.100-300 authorizations once or twice a year. Procedures were supported by HH NM staff including transportation of required radioactive drugs via underground tunnel from HH to CCMC. Education and training of staff involved in these studies and posting requirements were discussed, and the location of use was toured. All were found to be adequate. HH and CCMC staff were knowledgeable in procedural and radiation safety practices. Radioactive waste storage areas and loading dock scanners were inspected. The inspectors interviewed various types of radiation workers, observed daily activities being performed, and performed radiation surveys. The inspectors discussed the security of licensed material, 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. The licensee performed a mock demonstration of a Lu-177 infusion including the preparation of equipment by NM and the administration process in the dedicated infusion room. No concerns were noted.

2.3 Observations and Findings

2.3.1 High Dose Rate (HDR) Remote Afterloader

HH used an HDR to perform an average of 250 treatments per year for gynecological cancer. They also performed a small number of HDR treatments for skin cancers. The HDR was secured in a closet in the treatment room. The keys to the unit and console were locked in a desk drawer that only the Authorized Medical Physicists (AMPs) could access. Written directives, full calibrations, spot checks, and instrument calibrations were reviewed with no concerns noted. The required emergency postings were in place. Emergency training was provided to the majority of the staff; however, there was one AU and one AMP that were not trained in 2022 in violation of 10 CFR 35.610. HH submitted a request to remove the AMP in February of 2023 since they were not an active member of the program. The failure to provide the annual training to the AU was cited as a SL IV violation.

2.3.2 Lu-177 Written Directives (WD)

The licensee performed both Pluvicto™ and Lutathera® therapy infusions utilizing Lu-177. They were also involved in a nationwide 60-site research study using Pluvicto™. This study was performed under the approval of an Institutional Research Board and informed consent was obtained from all patients participating in the study. Two patients were participating in the study at HH.

A dedicated infusion room was used that included: space for the staff to observe the patient during the procedure, a dedicated chair that could be easily decontaminated should a spill occur, space for the IV lines adjacent to the chair, and a table to hold the shielded vial box to contain the dose while the infusion takes place. The infusion of the dose typically took 10-15 minutes; however, the patient was present between an hour and four hours depending on the infusion performed and the patient conditions.

Written directives were reviewed for both Lutathera® and Pluvicto™ infusions. There were no concerns noted with the Pluvicto™ written directives; however, the Lutathera® WDs did not contain the route of administration on them as required by 10 CFR 35.40(b)(2). The licensee had drafted a new form that did contain this information but had not started using it at the time of the inspection. This was cited as a SL IV violation.

2.3.3 Use of Jubilant's Ruby-Fill® Rb-82 generator

The licensee utilized a Jubilant Ruby-Fill® Rb-82 generator to conduct Rb-82 PET cardiac studies. There were three NMTs that primarily worked with the generator conducting the morning quality control. Because neither nationally recognized standards nor the manufacturer's instructions exist for this type of detector, the criteria in EGM 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages" were evaluated. Documentation of the generator elution and breakthrough levels were maintained in a logbook as well as each dosage administered. Written procedures for the use of the generator were kept and all NMT's training was current. The RSOs overseeing the program during the inspection period as well as the Authorized User (AU) had not completed the training. As a result, HH did not meet at least one of the criteria in EGM 13-003. Therefore, HH was not eligible for the use of enforcement discretion for failure to meet the requirements of 10 CFR 35.60 and 63, in accordance with EGM 13-003, and a SL IV violation was cited.

2.3.3 Eye Plaque Procedures

HH conducted six eye plaque treatments in 2022. The treatments were performed as in-patient procedures. A prescription was prepared by the AU and sent to Iso-Aid who performed the treatment planning, prepared the implant, and then sent it to HH. The patients remained in the hospital 3-5 days to assure the plaque did not come out and to monitor the patient until removal of the source. Nurses that cared for the patients were trained and provided with a dosimeter to evaluate their radiation exposure. The room was posted regarding the presence of radiation, visitor's access was controlled, and a log kept documenting each visitor and their time present. Patients were released following the removal of the plaque. Surveys of the patient were performed following the removal of the source; however, the person performing the survey was not documented. HH revised the form for this survey to include the person's name who performed it.

2.3.4 Microsphere (Y-90) Therapies

HH provided both TheraSphere and SIR-Sphere Y-90 therapies. There were four AUs approved for these procedures; however, there was one AU who primarily performed the procedures. In 2022, 20 TheraSphere and 11 SIR-Sphere therapies were performed. It was noted that HH used the manufacturer's documents for both types of administrations. The written directive provided by the manufacturer listed the location within the liver which was treated but did not designate the organ. HH agreed to specify the liver on the written directive going forward and placed it in a "drop down" menu to assure it was included.

3.0 Independent Radiation Measurements

All licensee staff were found to utilize radiation dosimetry. Independent surveys were conducted of the waste storage area, NM hot lab and injection areas, quiet rooms, Cardiology hot lab and stress labs and 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: 285185
Calibration expiration: 11/1/2023

4.0 Conclusions

During the inspection, it was observed that changes in corporate and site RSO reporting structure resulted in some challenges for the radiation safety program. The recently appointed RSO and the reporting structure were reviewed and will be valuated again at the next scheduled inspection to further assess the effectiveness of the February 2023 change in reporting structure.

During this inspection, three violations of NRC requirements were identified. The violations are:

1. 10 CFR 35.610(e) requires, in part, that licensees shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

   Contrary to the above, for March 2022, the licensee did not ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually. Specifically, one authorized user who was authorized for use of the high dose rate remote afterloader did not participate in the emergency training in 2022.

2. 10 CFR 35.40(b)(2) requires, in part, that written directives must contain the patient or human research subject's name and the following information for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration.

   Contrary to the above, from March 2021 until March 2023, the licensee's written directives did not contain the patient or human research subject's name and the following information for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration. Specifically, written directives for administrations of Lu-177, Lutathera® did not contain the route of administration.

3. 10 CFR 35.60(a) states, in part, for direct measurements performed in accordance with 10 CFR 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject. Furthermore, 10 CFR 35.60(b) states, in part, a licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

   Contrary to the above the licensee did not calibrate the instrument used to measure the activity of the dosage administered to each patient in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. Specifically, from March 2021 through March 2023, the licensee did not calibrate the dynamic detector used to measure the dosage of Rb-82 as part of their Rb-82 generator since neither nationally recognized standards nor the manufacturer's instructions exist for this type of detector. Further, at least one of the criteria in EGM 13-003 was not met. Specifically, the RSOs overseeing the program during the inspection period as well as the Authorized User (AU) had not completed training specific to the generator.

5.0 Exit Meeting

On March 16, 2023, the inspectors conducted an onsite debrief exit meeting with the licensee staff and management. The initial inspection findings and apparent violations were discussed. The licensee acknowledged the inspection findings. The final exit meeting was held June 29, 2023.

PARTIAL LIST OF PERSONS CONTACTED

*#Daniel Chiapatta	Physicist
*#Pam Cooke	Assistant Director, Radiology
#Cassandra Crowel	Director, Oncology Services
*Wioletta Chrostowski	Manager Non-Invasive Cardiology
*#Lane Duvall, M.D.	Authorized User
*#Sandra Phillips	Director, Radiology
*#Megan Hungerford	Manager, Nuclear Medicine
#Prasanta Karak, M.D.	Chair, Nuclear Medicine
*Steve Lee, MD	Chief/Chair Diagnostic Imaging
*#Erik Lyons	Assistant Radiation Safety Officer
*#Jason Marsden	Radiation Safety Officer
*#Victoria Nardi	Manager, Quality and Safety
#Gail Nelson	Director, Quality and Safety
*#Anthony Pacella	Assistant Radiation Safety Officer
#Joseph Phillips	Director, Oncology Services
*#Sandra Phillips	Director, Radiology
*#Andrew Salner, M.D.	Authorized User
*#Ted Steger	Physicist

Individual(s) present for onsite inspection debrief on March 16, 2022
* Individual(s) present for exit meeting on June 29, 2023

INSPECTION PROCEDURES USED

IP87130, Nuclear Medicine Programs

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 After Loader
HH: Hartford Hospital
NM: Nuclear Medicine
NMT: Nuclear Medicine Technologist NRC:
Nuclear Regulatory Commission
PET/CT: Positron Emission Tomography/Commuted Tomography
RSC: Radiation Safety Committee
RSO: Radiation Safety Officer
WD: Written Directive