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

June 27, 2023

EA-23-049

Joseph Corning, M.D.
Radiation Safety Officer
Hartford Healthcare Medical Group
1290 Silas Deane Highway
Weathersfield, CT 06109

SUBJECT: HARTFORD HEALTHCARE MEDICAL GROUP- NRC INSPECTION NO. 03028939/2023001 EXERCISE OF ENFORCEMENT DISCRETION

Dear Dr. Corning:

This letter refers to the inspection conducted on April 11-13, 2023, at your Middletown, Branford, Old Saybrook, Mystic, and Bloomfield, Connecticut facilities. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Nuclear Regulatory Commission's (NRC'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, independent radiation measurements, and interviews with personnel. A final exit meeting was held with Peter Armon, Erik Lyons, and you on April 27, 2023.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations (SLIV) of NRC requirements occurred. However, for both of the violations, the NRC is exercising discretion and not taking any enforcement action. Specifically, 10 CFR 35.60 requires, in part, that the licensee calibrate the instrument used to measure the activity of the dosage administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. However, the NRC determined that, as of April 11, 2023, the licensee was unable to calibrate the generator in accordance with 10 CFR 35.60. Specifically, there are no nationally recognized standards or specific calibration procedures for calibrating detectors in a dynamic mode (i.e., while liquids are flowing past the detector). Until such standards or procedures are established, the licensee cannot be in compliance with 10 CFR 35.60. Secondly, 10 CFR 35.63 requires, in part, that a licensee determine the activity of each dosage administered before each medical use. However, the NRC concluded that the licensee could not determine the activity of each dosage administered before each medical use. Specifically, due to the 76 second half-life of Rb-82 and the direct infusion of Rb-82 into the patient, users of this generator system are unable to measure patient dosages of Rb-82 prior to administration.

Although violations of 10 CFR 35.60 and 35.63 were identified which, in accordance with the NRC Enforcement Policy would normally be categorized at Severity level IV, Hartford HealthCare Medical Group (HHGM) has met all of the criteria addressed in NRC Enforcement

Guidance Memorandum (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 Doses,” dated April 18, 2013. Specifically: (1) HHMG has written test procedures to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer’s specifications; (2) HHMG has confirmed that the required infusion rate and radiation detector tests were performed within the last twelve months, and has maintained records documenting the performance and results of these tests; (3) all Authorized Users (AUs) for medical uses under 10 CFR 35.200 that use Rb-82 chloride have successfully completed training specific to the manufacturer and model of generator and infusion cart being used, and documentation of satisfactory completion of such training has been maintained; and (4) HHMG has recorded the activity of each dosage administered, as provided by the infusion cart. Therefore, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations.

In accordance with 10 CFR 2.390 of the NRC’s “Agency Rules of Practice and Procedure,” a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC 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 Netra Patel of my staff at 610-337-5364 or via electronic mail at Netra.Patel@nrc.gov.

Thank you for your cooperation.

Sincerely,

Anne E. DeFrancisco

Digitally signed by Anne E. DeFrancisco
Date: 2023.06.27 14:41:42 -04'00'

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

Docket No. 03028939
License No. 06-23559-01

Enclosure:
NRC Inspection Report 03028939/2023001

SUBJECT: HARTFORD HEALTHCARE MEDICAL GROUP- NRC INSPECTION NO. 03028939/2023001 EXERCISE OF ENFORCEMENT DISCRETION DATED JUNE 27, 2023.

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03028939/2023001
Enforcement Action No.	EA-23-049
Docket No.	03028939
License No.	06-23559-01
Licensee:	Hartford HealthCare Medical Group 1290 Silas Deane Highway Weathersfield, CT 06109
Locations Inspected:	420 Saybrook Road Middletown, CT 06457 711 Cottage Grove Road, Bloomfield, CT 06002 51 Main Street Old Saybrook, CT 06475 100 Perkins Farm Drive, Suite 301 Mystic, CT 06355 251 West Main Street Branford, CT 06405
Inspection Dates:	April 11-13, 2023

Inspector:

Netra S. Patel

Digitally signed by Netra S. Patel
Date: 2023.06.26 15:48:07 -04'00'

Netra Patel — Date
Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By:

Anne E. DeFrancisco

Digitally signed by Anne E. DeFrancisco
Date: 2023.06.27 14:40:58 -04'00'

Anne DeFrancisco, Chief — Date
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

EXECUTIVE SUMMARY

Hartford HealthCare Medical Group
NRC Inspection Report No. 03028939/2023001

A routine announced inspection was performed at Hartford HealthCare Medical Group (HHMC) on April 11-13, 2023. The inspection was conducted with regard to NRC radioactive materials license number 06-23559-01 and in accordance with inspection procedure 87130. The inspection focused on the performance of the licensee's program through interviews with licensee workers, demonstrations by workers performing licensed activities, independent measurements of radiation conditions at the licensee's facilities, and review of selected records.

During the inspection, two severity level IV (SLIV) violations of NRC requirements were identified. The violations involved the failure to calibrate the instrumentation used to measure the activity of unsealed byproduct material in accordance with 10 CFR 35.60 and the failure to determine the activity of each dosage administered before medical use in accordance with 10 CFR 35.63. However, in accordance with NRC Enforcement Guidance Memorandum (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 Doses," issued April 18, 2013, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspector 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.

b. Observations and Findings

Hartford HealthCare Medical Group (HHMG) is a private practice authorized for the use of 10 CFR 35.200 materials. There are six authorized locations of use: Middletown, Marlborough, Bloomfield, Old Saybrook, Mystic, and Branford. Only the Bloomfield location uses Rubidium-82 (Rb-82) generators for their PET studies in an onsite trailer. The Marlborough location was closed during the week of inspection; hence it was not inspected. The licensee contracts with Landauer to provide quarterly health physics services, such as performing audits, equipment quality control testing, training, sealed source inventory and leak testing, etc.

The Middletown location operates Monday through Friday from 7:00am – 3:30pm. The licensee only uses Tc-99m to perform stress and rest perfusion studies and an occasional MUGA scan. The licensee images approximately eight to twelve patients per day. All the dosages are received from Jubilant (Canton, MA) as unit doses and are assayed prior to administration. There is only one full time nuclear medicine technologist (NMT) at this location. The facility has one hot lab, two cameras, and one treadmill.

The Bloomfield location operates Monday - Tuesday for PET studies and Thursday - Friday for cardiac studies from 6:30am - 5pm. The licensee only uses Tc-99m to perform stress and rest perfusion studies. Rubidium-82 (Rb-82) generators are used for PET studies. The licensee images approximately twelve to thirteen patients per day for cardiac studies and approximately seven patients per day for PET studies. There are three full time NMTs at this location. The facility has one hot lab, two cameras, and two treadmills. PET studies are performed in a trailer located outside the building. All the dosages are received from Cardinal (Hartford, CT) as unit doses and are assayed prior to administration. Rb-82 generators are received from BRACCO.

The Old Saybrook location operates Monday, Tuesday, Wednesday, and Friday from 7:00am - 3:30pm. The licensee uses Tc-99m to perform stress and rest perfusion studies and images approximately four patients per day. There is one full time NMT at this location. The facility has one hot lab, one camera, and one treadmill. All dosages are received from Jubilant (Canton, MA) as unit doses and are assayed prior to administration.

The Mystic location operates Monday through Thursday from 7:00am - 3:30pm. The licensee uses Tc-99m to perform stress and rest perfusion studies and images approximately five patients per day. There is one full time NMT at this location. The facility has one hot lab, one camera, and one treadmill. All dosages are received from Cardinal (Hartford, CT) as unit doses and are assayed prior to administration.

The Branford location operates Monday through Friday from 7:30am - 4:00pm. The licensee uses Tc-99m for stress and rest perfusion studies and MUGA scans, and images approximately five patients per day. There is one full time NMT at this location. The facility has one hot lab, one camera, and one treadmill. All dosages are received from Jubilant (Canton, MA) as unit doses and are assayed prior to administration.

The NMTs were interviewed and showed a high level of competency. One of the sixteen AUs is also the Radiation Safety Officer (RSO) for the license. Currently, the RSO rotates between the Middletown, Marlborough, and Old Saybrook locations, and visits the other locations quarterly to review the radiation safety program.

Independent radiation surveys were taken during the inspection (Ludlum 2401P, SN 285217, Cal Date 01/05/2023) at each location. All readings were consistent with licensee postings and were within regulatory limits. The inspector reviewed documentation including audits, dosimetry reports, sealed source inventory and leak tests, instrument calibrations, dose calibrator quality control, dosimetry reports, wipe tests, and package receipt/return records.

2. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspector reviewed the material receipt, use, transfer, and control of the licensed program through interviews with workers, demonstrations by workers performing tasks regulated by NRC, and a review of selected records.

b. Direct Observations/Interviews and Record Review

The inspector toured the areas of use at each inspected location. The inspector observed the NMT at each location perform morning quality control on all hot lab equipment, an incoming package receipt survey, and a patient dose assay and administration. No concerns were noted. All the radioactive materials are stored in the hot labs. The hot labs are appropriately posted, and entry doors are kept locked to control access.

The inspector reviewed the following records at each inspected location: audits, sealed source inventory and leak tests, instrument calibrations, dose calibrator quality control, dosimetry reports, wipe tests, package receipt/return records, training records, and decay-in-storage records.

The following is a summary of the findings from the observations, interviews, and record review:

- HHMG has one BRACCO Sr-82/Rb-82 generator at the PET Center in Bloomfield, CT. Due to the inherent design of the generator, the licensee is unable to comply with 10 CFR 35.60 and 10 CFR 35.63. Specifically, 10 CFR 35.60 requires, in part, that the licensee calibrate the instrument used to measure the activity of the dosage administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. However, the NRC determined that, as of April 11, 2023, the licensee was unable to calibrate the generator in accordance with 10 CFR 35.60. Specifically, there are no nationally recognized standards or specific calibration procedures for calibrating detectors in a dynamic mode (i.e., while liquids are flowing past the detector). Until such standards or procedures are established, the licensee cannot be in compliance with 10 CFR 35.60. Secondly, 10 CFR 35.63 requires, in part, that a licensee determine the activity of each dosage administered before each medical use. However, the NRC concluded that the licensee could not determine the activity of each dosage administered before each medical use. Specifically, due to the 76 second half-life of Rb-82 and the direct infusion of Rb-82 into the patient, users of this generator system are unable to measure patient dosages of Rb-82 prior to administration. Although the violations of 10 CFR 35.60 and 35.63 are normally categorized as Severity Level IV; HHMG has met all of the criteria addressed in NRC Enforcement Guidance Memorandum (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 Doses,” dated April 18, 2013. Specifically: (1) HHMG has written test procedures to ensure that the infusion pump flowrate is consistent and accurate, and that the radiation detector meets the manufacturer’s specifications; (2) HHMG has confirmed that the required infusion rate and radiation detector tests were performed within the last twelve months, and has maintained records documenting the performance and results of these tests; (3) All AUs for medical uses under 10 CFR 35.200 that use Rb-82 chloride have successfully completed training specific to the manufacturer and model of generator and infusion cart being used, and documentation of satisfactory completion of such training has been maintained; and (4) HHMG has recorded the activity of each dosage administered, as provided by the infusion cart. Therefore, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations.

Independent Radiation Measurements

Independent radiation surveys were conducted at all of the inspected facilities. Survey locations included the hot labs, the camera rooms, the injection areas, and the treadmill rooms; the survey results were consistent with the licensee’s postings, the licensee’s results, and applicable regulatory limits.

Instrument type: Model # 2401-P
NRC S/N: 285217 calibration expiration date: 01/05/2024

c. Conclusions

During this inspection, two SLIV violation of NRC requirements were identified. The violations involved the failure to calibrate instrumentation used for direct measurements and determine the dosage of unsealed byproduct material prior to administration to each patient in accordance with 10 CFR 35.60 and 35.63. The NRC is exercising enforcement discretion in accordance with NRC Enforcement Guidance Memorandum (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 Doses," dated April 18, 2013.

3. Exit Meeting

On April 27, 2023, the inspector conducted a virtual Teams exit meeting with HHMG. During the meeting, the inspector discussed the observations, findings, and apparent violations. The inspector also discussed the use of enforcement discretion with the licensee. The licensee acknowledged the inspection findings.

Set next inspection date for: April 25, 2028.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

*Individual(s) present for final Teams exit meeting April 25, 2023

* Erik Lyons, Assistant RSO, Hartford HealthCare
* Joseph J. Corning, M.D., RSO, Authorized User
* Peter Armon, CNMT

INSPECTION PROCEDURES USED

IP 87130, Nuclear Medicine Programs, Written Directive Not Required

LIST OF ACRONYMS USED

ARSO	Assistant Radiation Safety Officer
AU	Authorized User
CFR	*Codof Federal Regulations*
EGM	Enforcement Guidance Memorandum
HHMC	Hartford Healthcare Medical Group
NM	Nuclear Medicine
NMT	Nuclear Medicine Technologist
NRC	Nuclear Regulatory Commission
PET	Position Emission Tomography
RSO	Radiation Safety Officer
SLIV	Severity Level IV