



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

July 27, 2020

Thomas von Dohlen, M.D.
Administrator and RSO
The Heart Center, PLLC
157 Skylar Drive
Lewisburt, WV 24901

**SUBJECT: THE HEART CENTER, PLLC - NRC INSPECTION NO. (03036669/2020001)
AND NOTICE OF VIOLATION**

Dear Dr. von Dohlen:

This letter refers to the inspection conducted on July 7, 2020, at your Lewisburg, WV facility. 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. An exit meeting with yourself and your staff was held on July 22, 2020.

Based on the results of this inspection, the NRC has determined that four Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's 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 violations were 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 will be (was) achieved is already adequately addressed on the docket and include: all exterior doors that do not lead to the supervised waiting room have been locked, a lockable cabinet has been installed in the hot lab for sealed source and patient dose storage, work flow has been adjusted to maintain constant control and/or surveillance of licensed material, a daily check list has been implemented to ensure daily constancy testing and daily surveys are performed and recorded as required, and a tag has been created for use on survey instruments that have lapsed in calibration. 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,

Donna Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03036669
License No. 47-30959-01

Enclosure:
Notice of Violation

cc w/ enclosure
State of West Virginia

THE HEART CENTER, PLLC - NRC INSPECTION NO. (03036669/2020001) AND NOTICE OF VIOLATION DATED JULY 27, 2020.

DOCUMENT NAME: [G:\WBL Documents\WBL Inspection Cover Letter\L47-30959-01.2020001.NOV.docx]

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DATE	EDE 27JUL2020	RLE 7/27/20			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

The Heart Center, PLLC
Lewisburg, WV

Docket No. 03036669
License No. 47-30959-01

During an NRC inspection conducted on July 7, 2020, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1802 requires, in part, that licensee's shall control and maintain constant surveillance of licensed material that is in a controlled area or unrestricted area and that is not in storage.

Contrary to above, the licensee did not control and maintain constant surveillance of licensed material that was in a controlled area and not in storage. Specifically, the licensee left a total of approximately 120 mCi of Tc-99m unit doses in the nuclear medicine hot lab, a controlled area, with no control or surveillance during the inspection.

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

- B. 10 CFR 35.60(a) states, in part, that 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. 10 CFR 35.60(b) states, in part, that a licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

Nationally recognized standards, IEEE N42.13, states, in part, that reference source checks should be performed and logged on each work shift during which the instrument is used. In the Capintec CRC -15 W Dose Calibrator Manual, the manufacturer recommends that a daily test, including a constancy test, be conducted at the beginning of each work day, prior to measuring any samples, which will be administered to patients.

Contrary to the above, the licensee did not calibrate the dose calibrator used to measure the activity of byproduct material before it is administered to each patient in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, the licensee did not perform a reference source check or constancy test for the dose calibrator with serial number 170980 on May 12, 2020, or May 13, 2020. Patient doses were assayed in the dose calibrator with serial number 170980 and administered on May 12, 2020, and May 13, 2020.

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

- C. 10 CFR 35.70 (a) states, in part, in addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use.

Contrary to the above, on May 12, 2020, and May 13, 2020, the licensee did not survey with a radiation detection survey instruments at the end of each day of use. Specifically, on those dates, radioactive doses were received and patients were administered dosages, yet no survey was performed at the end of either day of use.

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

- D. 10 CFR 35.61(a) states, in part, a licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 annually.

Contrary to the above, on October 31, 2016, and August 8, 2018, the licensee utilized a survey instrument with serial number 154158 to perform surveys. However, the instrument was not calibrated to show compliance with 10 CFR 20 and 35 annually. Specifically, the licensee calibrated the instrument with serial number 154158 on October 14, 2015, but did not calibrate it again until July 19, 2017. Furthermore, the same instrument with serial number 154158 was not calibrated again until September 20, 2018.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be 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.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 27 day of July 2020

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03036669/2020001
Docket No. 03036669
License No. 47-30959-01
Licensee: The Heart Center, PLLC
157 Skylar Drive
Lewisburg, WV 24901
Location(s): The Heart Center, PLLC
157 Skylar Drive
Lewisburg, WV 24901
Inspection Dates: July 7, 2020 with in office review concluding July 22, 2020.

Inspector(s):

Robin Elliott
Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

date

Elizabeth Engelmann
Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

date

Approved By: _____
Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

date

EXECUTIVE SUMMARY

The Heart Center, PLLC
NRC Inspection Report No. 03036669/2020001

A routine announced inspection was performed at The Heart Center, PLLC, on July 7, 2020. In office review concluded on July 22, 2020. The inspection was conducted with regard to NRC radioactive materials license number 47-30959-01; the inspection was conducted in accordance with inspection procedure 87130. The inspection focused on the performance of the licensee's program through direct observation of work activities, 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 four severity level IV (SLIV) violations of NRC requirements were identified. The violations involved the failure to: 1) control and maintain constant surveillance of licensed material in a controlled area; 2) calibrate instrumentation used to measure the activity of unsealed byproduct material in accordance with nationally recognized standards or the manufacturer's instructions; 3) survey with a radiation detection survey instrument at the end of each day of use; and 4) calibrate survey instruments annually.

REPORT DETAILS

1. **Organization and Scope of the Program**

a. 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.

b. Observations and Findings

At the time of the inspection The Heart Center, PLLC, was a private cardiologist practice authorized for CFR 35.200. The hours of operation were Monday through Thursday 0800 – 1630.

There was one full time Nuclear Medicine Technologist (NMT) for the facility. The Radiation Safety Officer (RSO) was the practice owner and the only Authorized User (AU); he was onsite daily. The site contracted with a consultant from National Physics Consultants to perform routine tasks such as coordinating survey meter calibrations with A&M Calibration Services, providing training, and conducting sealed source leak tests, sealed source inventories, dose calibrator calibrations, record reviews, and annual reviews of the radiation protection program. The consultant was onsite quarterly.

2. **Material Receipt, Use, Transfer, and Control**

a. Inspection Scope

The inspectors reviewed the material receipt, use, transfer, and control of the licensee's programs through direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and a review of selected records.

b. Observations and Findings

Direct Observations/Interviews/Demonstrations

The facility was a stand-alone building housing one cardiology practice. The facility included one hot lab, one dose calibrator, one treadmill, one injection area, and one imaging camera. The facility utilized unit doses of Tc-99m and occasionally Tl-201 for cardiac stress tests. The facility averaged four patients per day. Patient dosages were received from Cardinal Health's Princeton and Barboursville locations.

The licensee stored and utilized sealed sources in the hot lab. The licensee possessed four sealed sources at the time of the inspection. Radionuclides included Cs-137, Ba-133, and Co-57. During the inspection, the licensee performed a physical inventory of all sealed sources.

The inspectors toured the facility. The inspectors observed the NMT perform and demonstrate multiple tasks including package receipt, dose calibrator quality control, explanations of procedures to patients, and preparation/administration of patient dosages.

During the inspection a violation of 10 CFR 20.1802 was identified. Specifically, the inspectors arrive onsite and entered the facility through an unlocked exterior door. There was no access control or reception area from this exterior door. After entering the facility and proceeding down a hallway the inspectors were greeted by the NMT. The NMT led the inspectors to the hot lab to begin the inspection. At this time there were 6 unit doses with a total of approximately 120 mCi of Tc-99m sitting on a countertop in the hot lab. As the inspection progressed the NMT was asked to locate a sealed source. The source was not kept in the hot lab, it was in a room off a perpendicular hall. The NMT led one inspector down the hall, turned the corner, and proceeded down the perpendicular hallway. Meanwhile, the unit doses were left on the countertop the hot lab with the door open and unlocked. This is a violation of 10 CFR 20.1802 which requires, in part, that a licensee shall control and maintain constant surveillance of licensed material that is in a controlled area and that is not in storage. Additionally, upon discussion, the NMT stated that he routinely left patient doses unsupervised in the hot lab with patients being scanned on the camera. To correct this violation the licensee has locked the exterior doors except those that lead to the supervised waiting room. Additionally, a lockable cabinet was installed in the hot lab for storage of sealed sources and patient dosages. Finally, the licensee committed to bringing the patient to the injection area prior to retrieving the patient dose from the lockable cabinet.

Record Review

The following records were reviewed: written procedures for safe use of licensed material, daily area surveys, weekly area wipes, package receipt, package return, sealed source inventories, sealed source leak tests, dosimetry, waste disposal, instrument calibration, dose calibrator calibrations, annual audits, radiation safety training, and DOT/HAZMAT training. Some records were maintained electronically, and some were maintained on paper.

The following is a summary of the findings from the records review:

- The inspectors reviewed the dose calibrator records. The inspectors noted that the constancy test for dose calibrator was to be performed each day of use per nationally recognized standard IEEE N42.13 or in accordance with the manufacturer's recommendation. The nationally recognized standard indicates that reference source checks (constancy tests) should be performed and logged on each work shift during which the instrument is used. The manufacturer recommends that a daily test, including a constancy test, be conducted at the beginning of each workday, prior to measuring any samples, which will be administered to patients. The inspectors determined that the licensee did not calibrate the dose calibrators in accordance with the nationally recognized standard or the manufacturer's recommendations. Specifically, the licensee did not perform a reference source check or constancy test for the dose calibrator with serial number 170980 on May 12, 2020, or May 13, 2020. Patient doses were assayed in the dose calibrator with serial number 170980 and administered on May 12, 2020, and May 13, 2020. This is a violation of 10 CFR 35.60(a) and

35.60(b). The licensee has implemented a daily check list to ensure the daily constancy testing is performed and recorded as required.

- There were gaps in the daily survey records. Specifically, on May 12, 2020, and May 13, 2020, no area surveys were performed even though radioactive doses were received, and patients were administered dosages. This is a violation of 10 CFR 35.70(a) which requires, in part, in addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. The licensee has implemented a daily check list to ensure these surveys are performed and recorded as required.
- There were lapses in the calibration of survey instruments. Specifically, the licensee calibrated the instrument with serial number 154158 on October 14, 2015, but did not calibrate it again until July 19, 2017. Furthermore, the same instrument with serial number 154158 was not calibrated again until September 20, 2018. The licensee conducted and documented surveys on October 31, 2016, and August 8, 2018, with the uncalibrated survey instrument. This is a violation of 10 CFR 35.61(a) which requires, in part, a licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 annually. The licensee has created a tag that will be placed on survey instruments that have lapsed calibration in order to provide a clear indication that the instrument is past calibration and should not be utilized.

Independent Radiation Measurements

Independent radiation surveys were conducted in the hot lab, in the camera room, and in injection area; 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: 344918 calibration expiration date: December 6, 2020

Instrument type: Model # 2401-P
NRC S/N: 281353 calibration expiration date: January 30, 2021

c. Conclusions

During this inspection, four SLIV violations of NRC requirements were identified. The following are the violations:

- E. 10 CFR 20.1802 requires, in part, that licensee's shall control and maintain constant surveillance of licensed material that is in a controlled area or unrestricted area and that is not in storage.

Contrary to above, the licensee did not control and maintain constant surveillance of licensed material that was in a controlled area and not in storage. Specifically, the licensee left a total of approximately 120 mCi of Tc-99m unit doses in the nuclear medicine hot lab, a controlled area, with no control or surveillance during the inspection.

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

- F. 10 CFR 35.60(a) states, in part, that 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. 10 CFR 35.60(b) states, in part, that a licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

Nationally recognized standards, IEEE N42.13, states, in part, that reference source checks should be performed and logged on each work shift during which the instrument is used. In the Capintec CRC -15 W Dose Calibrator Manual, the manufacturer recommends that a daily test, including a constancy test, be conducted at the beginning of each work day, prior to measuring any samples, which will be administered to patients.

Contrary to the above, the licensee did not calibrate the dose calibrator used to measure the activity of byproduct material before it is administered to each patient in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, the licensee did not perform a reference source check or constancy test for the dose calibrator with serial number 170980 on May 12, 2020, or May 13, 2020. Patient doses were assayed in the dose calibrator with serial number 170980 and administered on May 12, 2020, and May 13, 2020.

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

- G. 10 CFR 35.70 (a) states, in part, in addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use.

Contrary to the above, on May 12, 2020, and May 13, 2020, the licensee did not survey with a radiation detection survey instruments at the end of each day of use. Specifically, on those dates, radioactive doses were received and patients were administered dosages, yet no survey was performed at the end of either day of use.

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

- H. 10 CFR 35.61(a) states, in part, a licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 annually.

Contrary to the above, on October 31, 2016, and August 8, 2018, the licensee utilized a survey instrument with serial number 154158 to perform surveys. However, the instrument was not calibrated to show compliance with 10 CFR 20 and 35 annually. Specifically, the licensee calibrated the instrument with serial number 154158 on October 14, 2015, but did not calibrate it again until July 19, 2017. Furthermore, the same instrument with serial number 154158 was not calibrated again until September 20, 2018.

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

3. Exit Meeting

On July 22, 2020, the inspectors conducted an exit meeting by telephone with The Heart Center. The inspection finding and violations were discussed. The licensee acknowledged the inspection findings and discussed corrective and preventative actions.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at entrance meeting
* Individual(s) present at on-site inspection debrief
+ Individual(s) present for telephonic exit meeting

#*+ Mike Hay
+ Thomas W. Van Dohlen, M.D., RSO

INSPECTION PROCEDURES USED

IP 87130, Nuclear Medicine Programs, Written Directive Not Required

LIST OF ACRONYMS USED

AU: Authorized User
CFR: Code of Federal Regulations
NMT: Nuclear Medicine Technologist
NRC: Nuclear Regulatory Commission
RSO: Radiation Safety Officer
SLIV: Severity Level IV