



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

August 12, 2020

Ganesh Asaithambi, M.D., Owner
Beckley Cardiology, PLLC
1832 Harper Road, 2nd Floor
Beckley, WV 25801

**SUBJECT: BECKLEY CARDIOLOGY, PLLC - NRC INSPECTION NO. (03039191/2020001)
AND NOTICE OF VIOLATION**

Dear Dr. Asaithambi:

This letter refers to the inspection conducted on July 9, 2020, at your Beckley, 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. On July 27, 2020, a telephonic exit meeting was held with yourself and your staff.

Based on the results of this inspection, the NRC has determined that two 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 violation(s); (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 and include: a visual aid checklist has been created and posted in order to remind staff of daily and weekly tasks. 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.

G. Asaithambi

2

Thank you for your cooperation.

Sincerely,

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

Docket No. 03039191
License No. 47-35564-01

Enclosure:
Notice of Violation

cc w/ enclosure
State of West Virginia
Kenneth Price, NMT

BECKLEY CARDIOLOGY, PLLC - NRC INSPECTION NO. (03039191/2020001) AND NOTICE OF VIOLATION DATED AUGUST 12, 2020

DOCUMENT NAME: [G:\WBL Documents\WBL Inspection Cover Letter\L47-35564-01.2020001.NOV.docx]

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OFFICE	RI:DNMS	RI:DNMS	RI:DNMS		
NAME	EEngelmann (EDE)	RElliott (RLE)	DJanda (DMJ)		
DATE	7/30/2020	8/12/2020	8/12/2020		

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Beckley Cardiology
Beckley, WV

Docket No. 03039191
License No. 47-35564-01

During an NRC inspection conducted on July 9, 2020, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Condition 14 of License Number 47-35564-01 requires, in part that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 29, 2019, (ADAMS Accession Number: ML19227A329) The application dated July 29, 2019, states, in part, that Beckley Cardiology will perform ambient dose rate surveys at the end of each day of use with a radiation detection survey meter in radiopharmaceutical preparation and administration areas.

Contrary to the above, on October 30, 2019, October 31, 2019, December 20, 2019, March 6, 2020, March 20, 2020, and May 8, 2020, the licensee did not conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 29, 2019. Specifically, on those dates, radioactive doses were received and licensed material was handled; however, no ambient dose rate survey was performed with a radiation detection survey instrument in the radiopharmaceutical preparation and administration areas at the end of the day.

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

- B. Condition 14 of License Number 47-35564-01 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 29, 2019 (ADAMS Accession Number: ML19227A329). The application dated July 29, 2019, states, in part, that Beckley Cardiology will survey weekly for removable contamination in all radiopharmaceutical storage, preparation, administration and waste storage areas.

Contrary to the above, during the weeks of October 28, 2019, November 4, 2019, December 16, 2019, March 16, 2020, and June 1, 2020, the licensee did not conduct its program in accordance with statements, representations, and procedures contained in the application dated July 29, 2019. Specifically, the licensee did not perform a survey for removable contamination in all radiopharmaceutical storage, preparation, administration and waste storage areas on a weekly basis.

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 12 day of August 2020

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03039191/2020001
Docket No. 03039191
License No. 47-35564-01
Licensee: Beckley Cardiology, PLLC
1832 Harper Road, 2nd Floor
Beckley, WV 25801
Location(s): Beckley Cardiology, PLLC
1832 Harper Road, 2nd Floor
Beckley, WV 25801
Inspection Dates: July 9, 2020 with in office review concluding July 27, 2020.

Inspector(s): _____
Robin Elliott
Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
_____ date

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

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

EXECUTIVE SUMMARY

Beckley Cardiology, PLLC
NRC Inspection Report No. 03039191/2020001

A routine announced inspection was performed at Beckley Cardiology, PLLC, on July 9, 2020. In office review concluded on July 27, 2020. This was the initial inspection for the licensee. The inspection was conducted with regard to NRC radioactive materials license number 47-35564-01 and 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 two severity level IV (SLIV) violations of NRC requirements were identified. The violations involved the failure to: 1) survey with a radiation detection survey instrument at the end of each day of use in accordance with license condition 14; and 2) perform weekly removable contamination surveys in accordance with license condition 14.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The license was issued on October 15, 2019. This was the initial inspection for the licensee. 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 Beckley Cardiology, PLLC, was a private cardiologist practice authorized for 10 CFR 35.200. The hours of operation were Monday through Friday 1300 – 1600. However, the hours changed frequently due to the COVID-19 Public Health Emergency.

There were two part time Nuclear Medicine Technologists (NMTs) at 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 Nuclear Medical Imaging and Physics to perform routine tasks such as coordinating survey meter calibrations, coordinating training, reviewing sealed source leak tests, and reviewing the radiation protection program. The consultant was onsite annually. The lead NMT performed routine tasks such as sealed source inventories, sealed source leak tests, and providing training. The inspectors assisted the NMT with subscribing to the NRC Medical Listserver.

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 treadmill, one injection area, and one imaging camera on the second floor. The licensee did not have a dose calibrator; they only utilized unit doses of

Tc-99m 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 two sealed sources at the time of the inspection. Radionuclides included Cs-137 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, well counter quality control, explanations of procedures to patients, and preparation/administration of patient dosages.

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, radiation safety training, and DOT/HAZMAT training. The annual program review had not been completed at the time of the inspection. All records were maintained on paper.

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

- There were gaps in the daily survey records. Specifically, on the following dates no area surveys were performed even though radioactive doses were received, and licensed material was handled: October 30, 2019; October 31, 2019; December 20, 2019; March 6, 2020; March 20, 2020; and May 8, 2020. This is a violation of license condition 14 which states, in part, that ambient dose rate surveys will be performed at the end of each day of use with a radiation detection survey meter in radiopharmaceutical preparation and administration areas.
- There were gaps in the weekly removable contamination surveys. Specifically, on the following weeks no removable contamination surveys were performed even though radioactive doses were received, and licensed material was handled: October 28, 2019; November 4, 2019; December 16, 2019; March 16, 2020; and June 1, 2020. This is a violation of license condition 14 which states, in part, that surveys will be performed for removable contamination in all radiopharmaceutical storage, preparation, administration and waste storage areas on a weekly basis.

Independent Radiation Measurements

Independent radiation surveys were conducted in the hot lab, in the camera room, and in the 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, two SLIV violations of NRC requirements were identified. The following are the violations:

- C. Condition 14 of License Number 47-35564-01 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 29, 2019 (ADAMS Accession Number: ML19227A329). The application dated July 29, 2019, states, in part, that Beckley Cardiology will perform ambient dose rate surveys at the end of each day of use with a radiation detection survey meter in radiopharmaceutical preparation and administration areas.

Contrary to the above, on October 30, 2019, October 31, 2019, December 20, 2019, March 6, 2020, March 20, 2020, and May 8, 2020, the licensee did not conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 29, 2019. Specifically, on those days, radioactive doses were received and licensed material was handled, and no ambient dose rate survey was performed with a radiation detection survey instrument in radiopharmaceutical preparation and administration areas at the end of the day.

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

- D. Condition 14 of License Number 47-35564-01 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 29, 2019 (ADAMS Accession Number: ML19227A329). The application dated July 29, 2019, states, in part, that Beckley Cardiology will survey weekly for removable contamination in all radiopharmaceutical storage, preparation, administration and waste storage areas.

Contrary to the above, during the weeks of October 28, 2019, November 4, 2019, December 16, 2019, March 16, 2020, and June 1, 2020, the licensee did not conduct its program in accordance with statements, representations, and procedures contained in the application dated July 29, 2019. Specifically, the licensee did not perform a survey for removable contamination in all radiopharmaceutical storage, preparation, administration and waste storage areas on a weekly basis.

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

The corrective action implemented to prevent a recurrence of these violations was that the NMT implemented a visual aid checklist and posted it in order to remind staff of daily and weekly tasks.

3. Exit Meeting

On July 27, 2020, the inspectors conducted an exit meeting by telephone with Beckley Cardiology. 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

#+ Kenneth Price
*+ Ganesh Asaithambi, M.D.

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