



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III

2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

May 20, 2013

Ms. Cari Dzanbazoff, CNMT
Radiation Safety Officer
Cardiovascular Associates, P.C.
27177 Lahser Road
Southfield, MI 48034

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03008670/2013002(DNMS)-
CARDIOVASCULAR ASSOCIATES, P.C.

Dear Ms. Dzanbazoff:

On April 16, 2013, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at the Cardiovascular Associates, P.C. office in Southfield, MI, with continuing in-office review through Monday, May 6, 2013. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The NRC in-office review included the evaluation of dosimetry information not available during the on-site inspection. A telephone exit meeting between you and Mr. Craffey of my staff was conducted on May 10, 2013, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as 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.

Based on the results of this inspection, an open item was identified regarding your radiation safety program. The open item involves the failure to wear individual monitoring devices as required by Condition 15.A of your NRC License.

No response to this letter is required. You will be notified by separate correspondence of the results of our review. In addition, please be advised that the number and characterization of the open item described in the enclosed inspection report may change as a result of further NRC review.

In accordance with Title 10 of the Code of Federal Regulations 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 or 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.

C. Dzanbazoff

-2-

Please feel free to contact me if you have any questions regarding this inspection. You can reach me at 630-829-9627.

Sincerely,

A handwritten signature in black ink, appearing to read "Tamara Bloomer". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Tamara Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-08670
License No. 21-15166-01

Enclosure:
IR 03008670/2013002(DNMS)

cc w/encl: State of Michigan

C. Dzanbazoff

-2-

Please feel free to contact me if you have any questions regarding this inspection. You can reach me at 630-829-9627.

Sincerely,

/RA/

Tamara Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-08670
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Enclosure:
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cc w/encl: State of Michigan

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-08670

License No.: 21-15166-01

Report No.: 03008670/2013002(DNMS)

Licensee: Cardiovascular Associates, P.C.

Facility: Cardiovascular Associates, P.C.
27177 Lahser Road
Southfield, MI 48034

Date(s): April 16, 2013
Continued in-office review through
May 6, 2013

Preliminary Exit Meeting: April 16, 2013

Final Exit Meeting: May 10, 2013

Inspector: Ryan Craffey, Health Physicist

Approved By: Tamara Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Cardiovascular Associates, P.C. NRC Inspection Report 03008670/2013002(DNMS)

This was a routine inspection of Cardiovascular Associates' radiation safety program at its Southfield, Michigan location of use. The inspection was conducted on April 16, 2013 with continued in-office review through May 6, 2013. The inspector reviewed several program areas including security of licensed material, radiation protection, dosimetry, training, and management oversight.

During the inspection, an open item was identified involving the failure to wear individual monitoring devices as required by Condition 15.A of the U.S. Nuclear Regulatory Commission (NRC) License Number 21-15166-01. This open item will continue to be reviewed by the NRC.

The licensee implemented corrective actions that included conducting an assessment to determine the technologist's approximate annual extremity dose for the period of time that dosimetry was not worn, reviewing the procedure for safe use of radiopharmaceuticals with all radiation staff, establishing spot checks by department management to verify that technologists continue to use their dosimetry in accordance with those procedures, and committing to examine future extremity monitoring results to verify that dosimetry is being worn in accordance with procedures.

Report Details

1 Program Overview

Cardiovascular Associates, P.C. is authorized under NRC Materials License No. 21-15166-01 to use licensed material for diagnostic nuclear medicine procedures permitted by 10 CFR Part 35.100 and 35.200. The group has locations of use in Southfield, MI and Warren, MI. The clinic currently has two Authorized Users on its license, and retains the services of a medical physics consultant to serve as Radiation Safety Officer (RSO), perform instrument calibrations and conduct quarterly audits.

At the Southfield location of use, the nuclear medicine department is normally staffed Mondays, Wednesdays and Thursdays by one part-time Nuclear Medicine Technologist (NMT), who performs approximately seven cardiac studies per day. The department receives unit doses of Technicium-99m from a licensed radiopharmacy in Lansing, MI.

The NRC previously inspected this licensee on March 21-22, 2013, at its Warren, MI office, and prior to that on October 22-23, 2008 at both locations of use. No violations of NRC requirements were identified during either inspection.

2 Personnel Monitoring

2.1 Inspection Scope

The inspector interviewed the RSO and select licensee staff, and reviewed the licensee's personnel exposure reports from the dosimetry vendor.

2.2 Observations and Findings

Although no principal activities were conducted on the day of the inspection, the NMT still demonstrated to the inspector the proper use of both the whole body and extremity monitoring devices, which the licensee issued to its staff on a monthly basis.

The inspector reviewed the licensee's personnel exposure reports, and found that the annual extremity doses recorded by the NMT's monthly ring badges were unusually low. The NMT stated that the reason why the annual doses were so low was because she had not routinely been wearing the ring badge for a period of several years.

License condition 15.A of Amendment 33 to NRC License 21-15166-01 requires the licensee to conduct its program in accordance with the application, dated January 28, 2004. Item 10, Section 8.24 of that application states that the licensee has developed and will 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. Item 4 of the licensee's procedure entitled "Rules for the Safe Use of Radiopharmaceuticals" states, in part, that a finger TLD ring will be worn with label facing the radiation source during the preparation, assay and administration of radioactive materials; and while holding patients injected with radiopharmaceuticals for image positioning purposes.

The licensee's corrective actions included conducting an assessment to determine the technologist's approximate annual extremity dose for the period of time that dosimetry was not worn, reviewing the procedure for safe use of radiopharmaceuticals with all radiation staff, establishing spot checks by department management to verify that technologists continue to use their dosimetry in accordance with those procedures, and committing to scrutinize future extremity monitoring results to verify that dosimetry is being worn in accordance with procedures.

The circumstances surrounding the failure to wear required dosimetry are under continuing NRC review and therefore this is considered an open item. The results of the agency's review of this matter will be provided in separate correspondence.

2.3 Conclusions

The licensee's failure to implement the procedure for safe use of unsealed licensed material as required by condition 15.A of NRC license 21-15166-01 is an open item. The circumstances surrounding this open item continue to be under NRC review.

3 **Other Areas Inspected**

3.1 Inspection Scope

The inspector toured the nuclear medicine department, interviewed the RSO and select licensee staff, and reviewed records related to the licensee's radiation safety program.

3.2 Observations and Findings

The inspector interviewed the RSO and NMT, who both demonstrated adequate knowledge of radiation safety principles and procedures. The inspector observed demonstrations of package receipt and area surveys, reviewed the licensee's measures for maintaining exposures as low as reasonably achievable (ALARA), and conducted independent and confirmatory surveys of the lab using a Ludlum 2403 survey meter with a Ludlum 44-38 energy-compensated Geiger-Müller detector calibrated on January 16, 2013.

The inspector also reviewed a selection of the licensee's records for package receipt, area surveys, dose calibrator quality control, waste disposal, and quarterly audits.

3.3 Conclusions

Based on these additional observations, the inspector did not identify any violations of NRC requirements.

4 **Exit Meeting Summary**

The NRC inspector presented preliminary inspection findings following the onsite inspection on April 16, 2013. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary, and acknowledged the findings presented. The inspector conducted a telephonic exit meeting with the licensee on May 10, 2013.

List of Personnel Contacted

- # Cari Dzanbazoff, RSO – Medical Physics Consultants
- Diane Dormal, NMT – Cardiovascular Associates, P.C.
- Susie Bokshan, Office Manager – Cardiovascular Associates, P.C.

Attended the telephonic exit meeting on May 10, 2013

Inspection Procedures Used

87130 – Nuclear Medicine Programs, Written Directive Not Required