UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

December 8, 2016

Naveen Lal, M.D.
Radiation Safety Officer
Allen County Cardiology
604 West Berry
Fort Wayne, IN 46802

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03035340/2016001(DNMS) – ALLEN COUNTY CARDIOLOGY

Dear Dr. Lal:

On October 18 and 21, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility, with continued in-office review through November 10, 2016. 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 in-office review included a review of and discussions about additional information you provided after the onsite inspection and your proposed corrective actions to the inspection findings. Ms. Deborah Piskura of my staff conducted a final exit meeting by telephone with you on November 10, 2016 to discuss the inspection findings. The enclosed report presents the results of the inspection.

The inspection examined activities conducted under your NRC license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations of your activities in progress, independent measurements, and interviews with personnel.

Four unresolved items were identified during this inspection regarding your radiation safety program. The unresolved items involve: (1) the licensee's process for performing surveys at the end of each day of use, as required by License Condition 15.A of NRC Materials License No. 13-32243-01; (2) the licensee's process for performing surveys for removable contamination each week, also as required by License Condition 15.A.; (3) the licensee's process for performing surveys of incoming packages containing radioactive material, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1906; and (4) the licensee's process for providing hazmat training to its employees, as required by 10 CFR 71.5(a) and 49 CFR 172.704(a) and (c).

Because these unresolved items remain under NRC review, no response for this letter is required at this time. You will be notified in separate correspondence of the results of our review of these unresolved items. Please be advised that the number and characterization of the unresolved items described in the enclosed inspection report may change as a result of further NRC review.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Please feel free to contact Ms. Piskura if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-35340
License No. 13-32243-01

Enclosure:
IR 03035340/2016001

cc w/encl: State of Indiana

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.	030-35340
License No.	13-32243-01
Report:	03035340/2016001(DNMS)
Licensee:	Allen County Cardiology
Location Inspected:	604 West Berry Fort Wayne, Indiana
Inspection Dates:	October 18 and 21, 2016
Final Exit Meeting:	November 10, 2016
Inspector:	Deborah A. Piskura, Senior Health Physicist
Approved by:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Allen County Cardiology
Fort Wayne, Indiana
NRC Inspection Report No. 03035340/2016001(DNMS)

This was a routine inspection conducted on October 18 and 21, 2016, to review the nuclear medicine activities. The inspection included in-office review through November 10, 2016. The purpose of the inspection was to evaluate the licensee's performance and compliance with NRC regulations and license conditions. The inspector reviewed several program areas including dose calibrator quality assurance tests, security, radiation protection, surveys, posting and labeling, and training.

During the inspection, several unresolved items were identified. These unresolved items will continue to be reviewed by NRC. The unresolved items included:

- The licensee's process for performing surveys at the end of each day of use as required by License Condition 15.A of NRC Materials License No. 13-32243-01;

- The licensee's process for performing surveys for removable contamination each week as required by License Condition 15.A;

- The licensee's process for performing surveys of incoming packages containing radioactive material as required by Title 10 of The *Code of Federal Regulations* (CFR) Section 20.1906; and,

- The licensee's process for providing hazmat training to its employees as required by 10 CFR 71.5(a) and 49 CFR 172.704(a) and (c).

The licensee implemented immediate corrective actions to address the unresolved items. The radiation safety officer (RSO) committed to increase the frequency of his reviews of the records of daily surveys, weekly wipe tests, and other radiation safety tasks.

Report Details

1 Program Scope and Inspection History

Allen County Cardiology (licensee) is a private group practice employing 10 individuals. The licensee is authorized to use licensed material permitted by 10 CFR 35.200. The licensee obtained its material in unit dose form from a licensed radiopharmacy. The nuclear medicine department was staffed with one full-time nuclear medicine technologist (NMT) who performed approximately 130-140 diagnostic cardiac procedures monthly. One physician was listed as an authorized user. The licensee retained the services of a consulting physicist who audited the radiation safety program on a semi-annual basis.

The NRC previously inspected the licensee's activities on November 22, 2011, and December 19, 2006, with no violations noted.

2 Management Oversight

2.1 Inspection Scope

The inspector reviewed the licensee's management of the radiation safety program and the radiation protection program reviews. The inspector interviewed the consultant physicist and the RSO. The inspector also reviewed selected audit reports for the 2015 to the year-to-date 2016 period.

2.2 Observations and Findings

The licensee's only physician authorized physician user is also the licensee's RSO. He reviewed and signed records associated with the radiation safety program.

The licensee retained the services of a consulting physicist who audited the radiation safety program every 6 months. The consultant provided a report to the licensee, "Records Audit" referencing the dates of the review and a checklist of records reviewed. The consultant initialed the respective column for each review. The consultant stated that he conducted separate annual reviews of the licensee's radiation safety program; these reports were not available during the inspection. The consultant reviewed and calculated dose calibrator linearity and accuracy, calibrated survey instrumentation, and leak tested sealed sources. The radiation safety officer reviewed and signed the consultant's reports for dose calibrator checks, survey instrument calibrations, and sealed source leak tests.

2.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector determined that no violations of NRC requirements were identified.

3 Surveys

3.1 Inspection Scope

The inspector toured the nuclear medicine department. The inspector interviewed selected staff and observed area ambient radiation surveys to evaluate the licensee's performance. The inspector reviewed records of wipe tests and ambient rate surveys maintained in the department.

3.2 Observations and Findings

According to the licensee's records reviewed as of October 18, 2016, no daily ambient rate surveys were performed between July and October 18, 2016. The licensee maintained this record in a log (table) format. The inspector also noted according to the licensee's records reviewed as of October 18, 2016, no weekly area contamination surveys were performed between August 29 and October 18, 2016. The licensee also maintained this record in a log (table) format. The NMT informed the inspector that he was behind on the recent records (approximately July/August 2016 to October 18, 2016). The inspector returned to the clinic on October 21, 2016, and the licensee presented the survey log sheets that were completed to date. The RSO and the technologist asserted that these records were available but misfiled and not easily retrievable during the first day of the inspection.

License Condition 15.A. (tie down) requires the licensee to conduct its program in accordance with the statements, representations, and procedures in its Application dated May 27, 2010. Item 10, "Radiation Protection Program," of the application, dated May 27, 2010, states that the licensee has developed and will implement written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70. Bullet 1 of the licensee's procedure, "Standard Operating Procedure-Area Surveys and Wipe Tests," requires, in part, "in radiopharmaceutical preparation, and administration areas, surveys are to be done at the end of each day with a low range GM (Geiger-Mueller) survey meter."

License Condition 15.A. (tie down) requires the licensee to conduct its program in accordance with the statements, representations, and procedures in its Application dated May 27, 2010. Item 10, "Radiation Protection Program," of the application, dated May 27, 2010, states that the licensee has developed and will implement written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70. Bullet 1 of the licensee's procedure, "Standard Operating Procedure –Area Surveys and Wipe Tests," requires, in part, "in any radiopharmaceutical preparation, and administration areas, a weekly wipe test will be performed."

The licensee's process for performing daily area survey and weekly area contamination surveys, as required by License Condition 15.A., are unresolved items. The circumstances surrounding the unresolved items continue to be under NRC review.

3.3 Conclusions

The inspector identified two unresolved items involving the licensee's processes for performing ambient surveys each day of use and weekly wipe surveys, as required by

License Condition 15.A. These matters are considered unresolved items and will continue to be reviewed by the NRC.

4 Training of Personnel

4.1 Inspection Scope

The inspector reviewed the training provided by the licensee to the personnel. The inspector interviewed the RSO and the NMT.

4.2 Observations and Findings

The licensee provided initial and annual radiation safety training to the nuclear medicine personnel. The licensee provided hazmat employee training to a hazmat employee on May 9, 2012, and February 26, 2016. The licensee maintained records of radiation safety and hazmat training for its employees.

Title 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180 and 390-397.

Title 49 CFR 172.704(a) specifies the elements of hazmat employee training as: (1) general awareness/familiarization training, (2) function-specific training, (3) safety training, (4) security awareness training, and (5) in-depth security training. Title 49 CFR 172.704(c) requires, in part, that a hazmat employee receive initial training, and recurrent training at least once every three years.

The licensee's process for providing recurrent training at least once every three years for its hazmat employees is an unresolved item. The circumstances surrounding this unresolved item continue to be under NRC review.

4.3 Conclusions

The inspector identified one unresolved item involving the licensee's process for providing hazmat training to its employees as required by 10 CFR 71.5(a) and 49 CFR 172.704(a) and (c). The NRC will continue its review of this unresolved item.

5 Receipt of Packages Containing Radioactive Material

5.1 Inspection Scope

The inspector interviewed the RSO and selected licensee personnel regarding receipt of packages containing radioactive material. The inspector reviewed records of surveys of incoming packages containing radioactive material.

5.2 Observations and Findings

On October 18, 2016, the licensee received two packages labeled with "Radioactive White I" labels. According to the licensee's records, no surveys were recorded of the

external surfaces for radioactive contamination and radiation levels. The licensee confirmed that it did not perform surveys of these two packages received on October 18, 2016.

Title 10 CFR 20.1906 requires the licensee to monitor the external surfaces packages labeled with a Radioactive White I or Yellow II label for: (1) radioactive contamination, and (2) radiation levels.

The licensee's process to monitor packages is an unresolved item. The circumstances surrounding this unresolved item continue to be under NRC review.

5.3 Conclusions

The inspector identified one unresolved item regarding the licensee's monitoring of incoming packages containing radioactive material, as required by 10 CFR 20.1906. The NRC will continue its review of this unresolved item.

6 Other Areas Inspected

6.1 Inspection Scope

The inspector reviewed other aspects of the licensee's radiation protection program which included security of licensed material, personnel monitoring, physical inventory and leak testing of sealed sources, labeling of containers, and postings. The inspector interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers, and reviewed selected records.

6.2 Observations and Findings

The inspector observed that the licensee personnel maintained constant surveillance of its licensed material. In addition, the inspector observed that the nuclear medicine hot lab remained secured.

The inspector determined that the licensee provided annual training to all staff working with or in the vicinity of licensed material. Through interviews, the inspector determined that the licensee staff understood security requirements for licensed material.

The inspector examined the sealed sources in the licensee's possession. The inspector noted that each source container had a clearly visible label identifying the radionuclides and source activities. The licensee's consultant performed inventories and leak tests of the sealed sources and documented the results in his reports.

The inspector observed that the licensee posted a copy of NRC Form 3. The inspector also observed that the rooms where licensed material was used and stored, were properly posted with "CAUTION-RADIOACTIVE MATERIALS" signs. The hot lab was also posted with emergency/decontamination procedures.

6.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector determined that no violations of NRC requirements were identified.

7 Exit Meeting Summary

The inspector discussed the preliminary conclusions with licensee management during the exit meeting conducted at the licensee's facilities on October 21, 2016, and during a November 10, 2016, teleconference. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

LIST OF PERSONNEL CONTACTED

Allen County Cardiolgoy
#*Naveen Lal, M.D., Radiation Safety Officer, Authorized User
*Ryan Kiel, Nuclear Medicine Technologist
Ashley Bidlack, Student Medical Assistant

Standard Nuclear Consultant
#Stan Burh, Consultant

*Individuals present at exit meeting
#Individual contacted by telephone

LIST OF INSPECTION PROCEDURES (IP) USED

IP 87130: Nuclear Medicine Programs, Written Directive Not Required

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Please feel free to contact Ms. Piskura if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-35340
License No. 13-32243-01

Enclosure:
IR 03035340/2016001

cc w/encl: State of Indiana

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