December 20, 2012

Jashu R. Patel, M.D.
Radiation Safety Officer
Jackson Cardiology Associates, P.C.
205 Page Avenue
Jackson, MI 49201

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03034118/2012001(DNMS)– JACKSON CARDIOLOGY ASSOCIATES, P.C.

Dear Dr. Patel:

On August 20, 2012, and November 7, 2012, with in office review through December 3, 2012, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at Jackson Cardiology Associates, P.C., Jackson, MI. The NRC in-office review included review and deliberations of records and information not available during the inspection. A preliminary exit meeting between you, and Michael Herr of my staff was conducted on November 7, 2012, 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 supply and require the use of individual monitoring devices as required by Title 10 Code of Federal Regulations (CFR), Section 20.1502(a) and License 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 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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site athttp://www.nrc.gov/reading-rm/adams.html http://www.nrc.gov/reading-rm/adams.html.

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 E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-34118
License No. 21-26715-01

Enclosure:
Inspection Report 03034118/2012001(DNMS)

cc w/encl: State of Michigan

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 E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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Enclosure:
Inspection Report 03034118/2012001(DNMS)

cc w/ encl: State of Michigan

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-34118
License No.:	21-26715-01
Report No.:	03034118/2012001(DNMS)
Licensee:	Jackson Cardiology Associates, P.C.
Facility:	Jackson Cardiology Associates, P.C. Jackson, MI 49201
Date(s):	August 20, 2012, and November 7, 2012, with Continued in-office review through December 3, 2012
Preliminary Exit Meetings:	November 7, 2012
Inspector:	Michael Herr, Health Physicist
Approved By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Jackson Cardiology Associates, P.C.
NRC Inspection Report 03034118/2012001(DNMS)

This was a routine inspection conducted on August 20, 2012, with continued in office review through December 3, 2012, including a second onsite inspection on November 7, 2012. The inspector reviewed several program areas including dose calibrator quality assurance tests, security, radiation protection, surveys, posting and labeling, and training.

During the inspection, an open item was identified involving the failure to provide and require the use of individual monitoring devices in accordance with Title 10 Code of Federal Regulations (CFR), Section 20.1502(a) and License Condition 15.A of NRC License Number 21-26715-01. This open item will continue to be reviewed by the U.S. Nuclear Regulatory Commission (NRC).

The licensee implemented corrective actions that included obtaining a contract with a dosimetry vendor, providing individuals with dosimetry, and requesting the licensee's medical consultant to determine the nuclear medicine technologist's (NMT) dose for the period of time that dosimetry was not worn.

Report Details

1. Program Overview

Jackson Cardiology Associates, P.C. was a small cardiology clinic authorized under NRC Materials License No. 21-26715-01 that employed one full time nuclear medicine technologist. The licensee is authorized to use licensed material permitted by 10 CFR Section 35.200. The licensee typically administers 5 - 6 doses of technicium-99m a day for cardiac studies. The licensee received unit doses from a licensed radiopharmacy. One physician was listed as authorized user on the license. The licensee retained the services of a consulting physicist who audited the radiation safety program on a quarterly basis.

The NRC previously inspected the licensee's activities on August 16, 2007, and May 7, 2002. A violation was noted during the August 2007 inspection involving the failure to post a "Caution Radioactive Materials" sign in an area containing radioactive materials as required by 10 CFR 20.1902(e). The May 2002 inspection had one violation for not exchanging dosimetry on a monthly basis as required by License Condition No. 14.

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 licensee's Radiation Safety Officer (RSO). The inspector also reviewed selected audit reports from 2008 to the year-to-date 2012.

2.2 Observations and Findings

Dr. Jashu Patel served as the primary authorized physician user and the licensee's RSO. The RSO is responsible for implementing the entire radiation safety program. The RSO was physically present at the clinic while nuclear medicine studies were performed.

The RSO indicated that he had designated the management of the dosimetry program to the nuclear medicine technologist. During an October 2012 meeting between the technologist and the RSO, the RSO discovered that the NMT had not paid the dosimetry vendor. As a result of not receiving payments, the vendor had not provided dosimetry service since the fourth quarter of 2011. The RSO made the decision after this discovery, to manage the dosimetry program himself and to procure the services of a new vendor for dosimetry service. The new dosimetry was provided to the technologist on November 5, 2012. See Section 3 for further information on the dosimetry issue.

2.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector did not identify any violations of NRC requirements.

3. Personnel Monitoring

3.1 Inspection Scope

The inspector interviewed the RSO, selected licensee personnel, reviewed select records, and the personnel exposure reports from the dosimetry vendor.

3.2 Observations and Findings

The licensee provided whole body and extremity dosimetry to its personnel working in the nuclear medicine department. The dosimetry was to be exchanged monthly for extremity badges and every calendar quarter for whole body badges.

On August 20, 2012, the inspector noted that the technologist was not wearing the assigned extremity dosimeter while administering technetium-99m to a patient for a cardiac study. The inspector inquired about the dosimetry and was informed that it was at the technologist's home. The technologist indicated that dosimetry would be worn the following day. The inspector brought this issue to the RSO, who indicated that a dose assessment would be performed and the dose received for the day would be added the in the individual's permanent dosimetry record.

The inspector requested to review dosimetry records of those assigned dosimetry. The technologist informed the inspector that the records were unavailable. The inspector then requested that the dosimetry records be sent to the Region III office for review. The requested dosimetry records were not provided timely and the inspector visited the facility on November 7, 2012, to review the records. During the November 7, 2012, inspection, the technologist informed the inspector that there were no dosimetry records and that dosimetry had not been worn since February 2012, when the fourth quarter 2011 dosimetry was lost.

Title 10 CFR 20.1502(a) requires in part, that each licensee monitor occupational exposure to radiation to radiation from license materials, and supply and require the use of individual monitoring devices for adults likely to receive in one year a dose greater than 500 millirem to the whole body and/or greater than 5000 millirem to an extremity.

License Condition 15.A of Amendment 4 of NRC License Number 21-26715-01 requires the license to conduct its program in accordance with the application, dated September, 13, 2011. Section 8.23, Item 10 of the application requires, in part, that the licensee either perform an evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20 (500 millirem whole body or 5000 millirem extremity) or provide dosimetry that meets the requirements in NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Medical Use Licensees."

The RSO indicated that corrective actions included obtaining a contract with a dosimetry vendor and providing individuals with dosimetry on November 5, 2102. In addition, the RSO indicated that he had requested his medical consultant to determine the dose for the nuclear medicine technologist for the period of time that dosimetry was not worn in 2011 and 2012.

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 our review of this matter will be provided under separate correspondence.

3.3 Conclusions

The licensee's failure to supply and require the use of dosimetry as required by 10 CFR 20.1502(a) and License Condition 15.A. is an open item. The circumstances surrounding this open item continue to be under NRC review.

4. Other Areas Inspected

4.1 Inspection Scope

The inspector toured the nuclear medicine department. The inspector interviewed selected staff, and observed area ambient radiation surveys and wipe surveys for removable contamination to evaluate the licensee's performance. The inspector reviewed select records including radiation survey and wipe survey data.

4.2 Observations and Findings

The inspector observed demonstrations of daily ambient surveys. The technologist demonstrated how she surveyed the surfaces with the GM probe. The inspector presented several scenarios to the technologist about action levels and spill responses; the responses were adequate. The inspector observed a patient administration of technetium-99m for a cardiac study.

The inspector performed independent surveys of the hot lab, treadmill area and imaging areas. The inspector did not identify any areas with measurements above background.

The inspector attempted to review records but was informed by the technologist that the records were unavailable during the inspection on August 20, 2012. The inspector requested that selected records be sent to the inspector for review. The licensee provided the selected records, weekly survey records, package receipt records, and waste disposal records, which were reviewed in the office by the inspector.

4.3 Conclusions

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

5. Exit Meeting Summary

The inspector discussed the preliminary conclusions with licensee management during the exit meetings conducted at the licensee's facilities on August 20, 2012, and November 7, 2012.

LIST OF PERSONNEL CONTACTED

Jackson Cardiology Associates, P.C.
Jashu Patel, M.D., RSO, Authorized User
Marcia Doyle, Nuclear Medicine Technologist