August 8, 2013

EA-13-134

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) AND INVESTIGATION REPORT NO. 3-2013-005 - JACKSON CARDIOLOGY ASSOCIATES, P.C.

Dear Dr. Patel:

On August 20, 2012, and November 7, 2012, with continued in-office review through December 3, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Jackson, Michigan. The details of the inspection were documented in NRC Inspection Report No. 03034118/2012001(DNMS) issued on December 20, 2012. During the inspection, an unresolved item was identified that required further NRC review. The NRC Office of Investigations (OI) began an investigation on December 3, 2012, and the investigation was completed on June 5, 2013. A factual summary of the NRC investigation is enclosed.

Based on the results of the inspection and investigation, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The first apparent violation involves the willful failure, by your nuclear medicine technologist, to wear whole body and extremity dosimetry, from July 1 until November 5, 2012, which is contrary to Title 10 *Code of Federal Regulations* (CFR), 20.1502(a)(1) and License Condition 15.A of your NRC license. The second apparent violation involves the technologist willfully providing the NRC with incomplete and inaccurate information regarding wearing of dosimetry during the inspection on August 20, 2012, which is contrary to 10 CFR 30.9. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you at the inspection exit meeting on November 7, 2012.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in this letter and Inspection Report No. 03034118/2012001(DNMS) within 30 days of the date of this letter, (2) request a Predecisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR). If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, the PEC will be closed to public observation since information related to an Office of Investigations report will be discussed and the report has not been made public. Please contact Aaron McCraw at (630) 829-9650 within 10 days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to An Apparent Violation in NRC Inspection Report 03034118/2012001(DNMS); EA-13-134" and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance was or will be achieved. In addition, please ensure your response includes the corrective actions implemented by you and your staff regarding the importance of providing complete and accurate information to the NRC at all times. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC's website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at (877) 733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In addition, please be advised that the number and characterization of apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter, including resolution of the unresolved item identified during the inspection.

In accordance with 10 CFR 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's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

Please feel free to contact Mr. Ken Lambert of my staff if you have any questions concerning this inspection. You can reach Mr. Lambert at (630) 829-9633.

Sincerely,

/RA/

Patrick L. Louden, Acting Director
Division of Nuclear Materials Safety

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

Enclosure:
Factual Summary of NRC Investigation

cc w/encl: State of Michigan

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Patrick L. Louden, Acting Director
Division of Nuclear Materials Safety

Docket No. 030-34118
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Enclosure:
Factual Summary of NRC Investigation

cc w/encl: State of Michigan

Distribution w/encl:
See next page

*See previous concurrence
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DATE	08/02/13		08/02/13		08/07/13		08/02/13	
OFFICE	HQ OE		HQ OGC		RIII DNMS		RIII	
NAME	RZimmerman[1]		CScott[2]		PLLouden			
DATE	08/07/13		08/07/13		08/08/13			

[1] Concurrence provided by email from Kerstun Day dated August 7, 2013.
[2] No legal objection provided by email from Joseph Gilman dated August 6, 2013.

OFFICIAL RECORD COPY

Letter to Jashu R. Patel, M.D. from Aaron T. McCraw dated August 08, 2013

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03034118/2012001(DNMS) AND INVESTIGATION REPORT NO. 3-2013-005 - JACKSON CARDIOLOGY ASSOCIATES, P.C.

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FACTUAL SUMMARY OF NRC INVESTIGATION

On December 3, 2012, the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a nuclear medicine technologist (NMT) at Jackson Cardiology Associates in Jackson, Michigan, willfully failed to comply with NRC requirements by not wearing dosimetry while performing an activity that required dosimetry, and whether the NMT willfully failed to provide complete and accurate information to an NRC inspector during an inspection. The investigation was completed on June 5, 2013, and was documented in NRC OI Report No. 3-2013-005.

On August 20, 2012, an NRC inspector (accompanied by his supervisor) conducted a routine inspection of Jackson Cardiology Associates, an NRC materials licensee. During this inspection, the inspector observed the NMT not wearing required dosimetry. When the inspector inquired about the dosimetry, the NMT responded that she had left the devices on her lab coat at home. The NMT acknowledged that dosimetry was required for the normal duties of her work, and assured the inspector that she would retrieve the dosimetry and bring them to work the following day. Additionally, the inspector noted that the licensee records, including the dosimetry records, were disorganized and incomplete.

On November 7, 2012, the inspector returned to Jackson Cardiology to perform a follow up inspection. At that time, the NMT admitted that she had lied to the inspector during the previous inspection. The NMT informed the inspector that she had not left her dosimetry at home, but had actually lost it in February 2012, and had not replaced it since that time.

The owner of Jackson Cardiology is also the Radiation Safety Officer (RSO) at the site. Based on the subsequent inspection and testimony, the RSO was not aware of the dosimetry problems. The NMT was in charge of ensuring everything concerning dosimetry was in compliance with NRC requirements, as she was the sole NMT and only person performing the relevant work.

During an OI interview, the NMT admitted that, for the latter half of 2010 until late June 2012, she was wearing the required dosimetry but not having it analyzed or replaced on a regular basis. From late June 2012 until late October 2012, the NMT admitted she was not wearing any dosimetry at all. This was a result of the NMT not having made payments to Jackson Cardiology's dosimetry vendor.[1] The vendor account records confirmed that the NMT had not been regularly sending her dosimetry for analysis, and her final submission was in the last quarter of 2011. The NMT testified that business for the office had declined and she was embarrassed to alert the RSO to the fact that she had missed payments to the dosimetry vendor, and was no longer sending her dosimetry to be analyzed and replaced. The NMT stressed that her failure to notify the RSO was in no way a result of a chilled work environment.

Once the RSO became aware of the situation as a result of the NRC inspection, he immediately took the responsibilities of managing the dosimetry contract and paperwork away from the NMT.

[1] The NMT ultimately gave three different explanations as to why she was not wearing the required dosimetry: (1) her dosimetry was left at home during the first inspection; (2) she lost her dosimetry in February 2012; and (3) she failed to pay the vendor and stopped wearing her dosimetry after her vacation in June 2012. OI verified that the third story seems to be the most accurate explanation.

The RSO immediately paid the past due amounts owed to the vendor, and acquired a new dosimetry contract from another vendor. Since November 5, 2012, all appropriate dosimetry was worn and sent for analysis and replacement at appropriate intervals.

The NMT admitted to OI that (1) she was aware of the requirements to wear the appropriate dosimetry; (2) she lied to the NRC inspector during the August 20, 2012 inspection; and (3) she had deliberately failed to comply with the applicable dosimetry requirements.

Based on the evidence, the OI investigation substantiated that the NMT willfully failed to provide complete and accurate information to the NRC inspector during the inspections, and willfully failed to comply with NRC requirements by not wearing dosimetry while working in an activity that required wearing dosimetry.