



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

Region III
2443 Warrenville Road, Suite 210
Lisle IL 60532-4352

October 30, 2013

EA-13-134

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

**SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF
CIVIL PENALTY – \$3,500; 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. The NRC Office of Investigations (OI) began an investigation on December 3, 2012, and the investigation was completed on June 5, 2013. Based on the results of that inspection and investigation, the NRC identified two apparent willful violations of NRC requirements. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you on November 7, 2012.

In our letter dated August 8, 2013, we provided you with the opportunity to address the apparent violations by attending a predecisional enforcement conference, requesting Alternate Dispute Resolution (ADR), or providing a written response before we made our final enforcement decision. In a letter dated August 28, 2013, you provided a response to the apparent violations.

Based on the information developed during the inspection and investigation, and the information that you provided in your letter dated August 28, 2013, the NRC has determined that two willful violations of NRC requirements occurred. The violations are cited in the Notice of Violation (Notice) and the circumstances surrounding them are described in detail in our letters dated December 20, 2012, and August 8, 2013.

On August 20, 2012, an NRC inspector observed your nuclear medicine technologist (NMT) not wearing required dosimetry (film and ring badges). The NMT indicated that she had left the badges on her lab coat at home. The NMT assured the inspector that she would retrieve the badges and bring them to work the following day. On November 7, 2012, the inspector returned 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. 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. The first violation involved the willful failure by the NMT 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 violation involved the NMT 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 overarching root cause of the violations was your failure, as owner and Radiation Safety Officer (RSO) to provide adequate oversight of the radiation safety program with respect to dosimetry. The root cause of the dosimetry violation was the NMT's failure to provide you bills for the dosimetry service for payment, because you were questioning the amount of the bills and if they were necessary. The root cause of the 10 CFR 30.9 violation was the NMT's deliberate action to mask Jackson Cardiology Associates' noncompliance with the regulations. Since the two violations are closely related, the NRC has chosen to group the violations as a Severity Level III problem.

Willful violations of NRC requirements cannot be tolerated. Although the underlying failure to monitor the NMT had limited safety significance because of the limited dose rates, the NMT's failure to wear required dosimetry prevented you from monitoring and evaluating the NMT's exposure to radiation. The NMT's failure to provide complete and accurate information impacted the NRC regulatory process. Therefore, the violations have been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III problem. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is normally considered for a Severity Level III problem.

Because the violations were willful, the NRC considered whether credit was warranted for both *Identification* and *Corrective Action* in accordance with the civil penalty assessment process described in Section 2.3.4 of the Enforcement Policy. Credit was not warranted for *Identification* because the NRC identified the violations. Credit was warranted for *Corrective Action*. Your corrective actions included, but were not limited to: required dosimetry was obtained from a vendor; dosimetry reports are now mailed directly to your attention; you assumed responsibility for purchasing and paying for dosimetry; you routinely audit the staff for compliance with dosimetry requirements; and you will not delegate dosimetry responsibility to any other individual. Additionally, the NMT has been retrained and counseled as to the importance of supplying accurate and complete information to the NRC and to all individuals involved in the facility's licensed activities; you increased your oversight and supervision of the NMT and review the NMT's work monthly; you will meet with the physics consultant during his quarterly audit to discuss any regulatory compliance issues; you will review and sign the physics consultant's quarterly audit report; and you will ensure that there is an adequate safety culture within your facility.

Therefore, to emphasize the need for your adequate oversight of the radiation safety program, the importance of providing complete and accurate information to the NRC, and that willful violations of NRC requirements cannot be tolerated, I have been authorized, after consultation

with the Director of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$3,500. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations, and the date when full compliance was achieved, was adequately addressed on the docket in NRC Inspection Report No. 03034118/2012001(DNMS) dated December 20, 2012, and in your response dated August 28, 2013. Therefore, you are not required to respond to this letter unless the description therein 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.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Generally, the NRC is willing to discuss the resolution of three potential issues: 1) whether violations occurred; 2) the appropriate enforcement action; and 3) the appropriate corrective actions for the violation. Additional information concerning the NRC's ADR program can be found at <http://www.internal.nrc.gov/OE/ADR/post-invest-adr-home.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance as necessary. Please contact the ICR at (877) 733-9415 within 10 days of the date of this letter if you are interested in pursuing this issue through the ADR program. You may also contact Steven Orth, Enforcement Officer, at (630) 810-4370 for additional information. If you decide to pursue ADR, please contact Mr. Orth within 10 days of the date of this letter.

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 respond, 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>.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

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

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee Only)

cc w/encl 1: State of Michigan

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Jackson Cardiology Associates, P.C.
Jackson, Michigan

Docket No. 030-34118
License No. 21-26715-01
EA-13-134

During an NRC inspection conducted on August 20, 2012, and November 7, 2012, with continued in-office review through December 3, 2012, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and Title 10 of the Code of Federal Regulations (10 CFR) Section 2.205. The particular violations and associated civil penalty are set forth below:

- A. License Condition 15.A of NRC License Number 21-25715-01 requires, in part, that the licensee conduct its program in accordance with statements, representations, and procedures contained in an application, dated September 13, 2011. Section 8.23, Item 10, of the application states that the licensee either will perform a prospective 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 or will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Volume 9, Revision 2. "Criteria" under Section 8.23, Item 10 of NUREG-1556, Volume 9, Revision 2 states, in part, that the license must either demonstrate 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 or will monitor external and/or internal occupational radiation exposure, if required by 10 CFR 20.1502.

10 CFR 20.1502(a)(1) requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and supply and require the use of individual monitoring device by adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, from July 1 until November 5, 2012, the licensee failed to either demonstrate 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, or supply and require the use of individual monitoring device by adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

- B. 10 CFR 30.9 states, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

Contrary to the above, on August 20, 2012, a nuclear medicine technologist (NMT), an employee of Jackson Cardiology Associates, P.C., an NRC licensee, provided the Commission with information that was not complete and accurate in all material respects. Specifically, the NMT informed an NRC inspector that she had left her dosimetry at home when she knew that she misplaced her dosimetry at the end of June 2012, and neglected to inform the inspector that she had not made payments to the dosimetry vendor to continue the contract, and had not obtained the services of a replacement vendor. The information was material to the NRC because it was used as the basis for a violation of License Condition 15.A of NRC License No. 21-25715-01 and 10 CFR 20.1502 (a).

Notice of Violation and Proposed
Imposition of Civil Penalty

-2-

This is a Severity Level III problem (Sections 6.3, 6.7, and 6.9).
Civil Penalty – \$3,500

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03034118/2012001(DNMS) dated December 20, 2012, and in your response dated August 28, 2013. 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, EA-13-134," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

You may pay the civil penalty proposed above, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, a statement ("Statement as to Payment of Civil Penalty") indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should you fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should you elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, your response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205, should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. Your attention is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., "Reply to a Notice of Violation," "Statement as to Payment of Civil Penalty," and "Answer to a Notice of Violation," should be addressed to:
Roy P. Zimmerman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission,
One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to
Cynthia D. Pederson, Regional Administrator, U.S. Nuclear Regulatory Commission,
Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352.

If you chose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in 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 or proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 30th day of October 2013

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 respond, 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>.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

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

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2. NUREG/BR-0254 Payment Methods (Licensee Only)

cc w/encl 1: State of Michigan

SEE PREVIOUS CONCURRENCE

FILE NAME: G:\ORAI\IICS\ENFORCEMENT\Cases\Enforcement Cases 2013\EA-13-134 Jackson Cardiology\EA-13-134 Jackson Cardiology Final Action - FINAL.docx

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DATE	09/30/13	10/02/13	10/02/13	10/02/13	10/28/13	10/07/13	10/28/13	10/30/13	10/30/13

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¹ OE concurrence received via email from D. Kerstun on October 28, 2013, 2013

² OGC "No legal objection" received via email from J. Gilman on October 7, 2013

³ FSME concurrence received via email from M. Burgess on October 28, 2013, 2013

Letter to Jashu R. Patel from Cynthia D. Pederson dated October 30, 2013

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF
CIVIL PENALTY – \$3,500; NRC ROUTINE INSPECTION REPORT
NO. 03034118/2012001(DNMS) AND INVESTIGATION REPORT
NO. 3-2013-005 - JACKSON CARDIOLOGY ASSOCIATES, P.C.

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