



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

November 1, 2016

Docket No. 15000019

MD License No. MD-33-195-01

Alexander P. Kurikeshu, M.D.
President and Radiation Safety Officer
American Cardiovascular Imaging, LLC
8675 Cherry Lane
Laurel, MD 20707

**SUBJECT: NRC INSPECTION REPORT NO. 15000019/2014001, AMERICAN
CARDIOVASCULAR IMAGING, LLC, WASHINGTON, D.C. SITE AND NOTICE
OF VIOLATION**

Dear Dr. Kurikeshu:

On January 27, 2014, Janice Nguyen of this office conducted a safety inspection at 1160 Varnum Street, #114, Washington, D.C. of activities authorized under the license listed above. Your activities in NRC jurisdiction are authorized by a general license granted by 10 CFR 150.20(a). The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in your correspondence dated September 8, 2015, was also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection on October 27, 2016.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that two Severity Level 4 violations of NRC requirements occurred. The violations involved: 1) the failure to obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client as required by 10 CFR 35.80(a)(1); and 2) the failure to label the Cobalt-57 flood source with labels specified for the material in the 49 CFR 172.101 table and in this subpart (i.e., Radioactive Yellow II) as required by 49 CFR 172.400(a). The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

In a telephone conversation on January 28, 2014, you committed to labelling the Cobalt-57 flood source with a Radioactive Yellow II label and appropriate Transportation Index (TI). You also committed to developing a mobile client agreement. You submitted the signed mobile client agreement on September 8, 2015. During an inspection conducted on October 19, 2016 (2016-001), the inspector was able to verify that the signed agreement was in place and that the Cobalt-57 flood source was labelled with a Radioactive Yellow II label and appropriate Transportation Index (TI). During our inspection exit meeting on October 27, 2016, you confirmed that American Cardiovascular Imaging, LLC is committed to radiation safety and to compliance with NRC regulations and licensed conditions. The violations for the 2014-001 inspection were closed out and a clear inspection report will be issued for 2016-001.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our records and in your correspondence dated September 8, 2015, and was additionally verified during your NRC inspection conducted on October 19, 2016 (2016-001). Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your September 8, 2015, correspondence 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), 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 document system (ADAMS), accessible from the NRC 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 available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

A. Kurikeshu

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Please contact Janice Nguyen at (610) 337-5006 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc: State of Maryland
District of Columbia

A. Kurikeshu

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Please contact Janice Nguyen at (610) 337-5006 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc: State of Maryland
District of Columbia

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	JNguyen/jn		JDwyer/jd					
DATE	11/1/16		11/1/16					

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NOTICE OF VIOLATION

American Cardiovascular Imaging, LLC
Laurel, MD

Docket No. 15000019
MD License No. MD-33-195-01

During an NRC inspection conducted on January 27, 2014 for which a telephone exit meeting was held on October 27, 2016, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.80(a)(1) requires, in part, that a licensee providing mobile medical service shall obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client.

Contrary to the above, as of January 27, 2014, American Cardiovascular Imaging, LLC (ACI), a licensee providing mobile medical service, did not obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client. Specifically, ACI had a contract in place with its client, but it did not clearly delineate the authority and responsibility of ACI and its mobile client.

This is a Severity Level IV violation (NRC Enforcement Policy Example 6.3.d.9.).

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

49 CFR 172.400(a) requires, in part, that each person who offers for transportation or transports a hazardous material shall label the package or contamination device with labels specified for the material in the 172.101 table and in this subpart (i.e., Radioactive Yellow II).

Contrary to the above, as of January 27, 2014, ACI did not label the package or contamination device with labels specified for the material in the 172.101 table and in this subpart (i.e., Radioactive Yellow II). Specifically, the Cobalt-57 flood source transported to the client site was not labeled as Radioactive Yellow II as required.

This is a Severity Level IV violation (NRC Enforcement Policy Example 6.3.d.4.).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 1st day of November 2016