



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

August 29, 2014

Docket No. 03037806
EA-14-065

License No. 55-31325-01

Kendall Griffith, M.D.
Cardiovascular Associates of
the Virgin Islands, PLLC
4100 Sion Farm Shopping Center
Suite 5
Christiansted, St. Croix, VI 00820

SUBJECT: NRC INSPECTION REPORT NO. 03037806/2012001 AND NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2012-042, CARDIOVASCULAR ASSOCIATES OF THE VIRGIN ISLANDS, PLLC, CHRISTIANSTED, ST. CROIX, VIRGIN ISLANDS SITE AND NOTICE OF VIOLATION

Dear Dr. Griffith:

On February 9, 2012, Penny Lanzisera and Joseph Nick of this office conducted a safety inspection at the Cardiovascular Associates of the Virgin Islands, PLLC (CAVI) facility of activities authorized by the above listed NRC license. The inspection continued in office until July 10, 2014. 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 inspectors, interviews with personnel, and a selective examination of representative records. Additional information provided in your written correspondence dated February 29, 2012 (ML12073A303¹), and email correspondence with your prior nuclear medicine technologist on February 14, 2014, were also examined as part of the inspection. The findings were discussed with you at the conclusion of the inspection. Additionally, on March 21, 2014, the NRC Office of Investigations (OI) completed an investigation to determine, in part, whether the CAVI Radiation Safety Officer (RSO) willfully: (1) submitted to the NRC a license amendment request on March 14, 2011, that was not signed by CAVI management; and (2) caused CAVI to receive radioactive sources for which CAVI was not authorized.

For the first concern, based upon evidence gathered during the OI investigation, although the CAVI RSO did submit the March 14, 2011, license amendment requesting NRC authorization to provide leak testing services to other licensees without obtaining the signature of an authorized CAVI management representative, the NRC concluded that the RSO did not do so willfully. Even so, the NRC concluded that submittal of the unauthorized license amendment application constituted a violation of 10 CFR 35.12(a). In accordance with the NRC Enforcement Policy,

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS.

the NRC assessed the violation at Severity Level (SL) IV. The violation is cited in the enclosed Notice of Violation (Notice) because it was identified by the NRC.

As pertains to the second concern, the NRC concluded that the CAVI RSO willfully (in careless disregard) caused CAVI to receive sealed sources from a Colorado Agreement State licensee (NC Systems) not authorized to redistribute them, in violation of 10 CFR 35.65(b). Specifically, the NRC identified that, in February-March 2011, NC Systems (of which the CAVI RSO was a co-owner and the RSO, at the time) sold and shipped to CAVI two cobalt-57 sealed calibration sources that NC Systems had purchased and received from the manufacturer. However, the NC Systems' Colorado license did not authorize the company to redistribute licensed material.

NC Systems had previously been authorized by its Colorado license to be a service provider, and had performed leak testing, calibration, and source procurement and other services for NRC and other Agreement State licensees. However, when NC Systems renewed its Colorado license in 2009, the company requested removal of the service provider authorization and, therefore, could no longer perform these activities. In February 2011, the State of Colorado inspected NC Systems and identified that the company was still conducting service provider activities, in part, because a number of the NC Systems staff were not aware that the license had been changed. Based on the NRC OI investigation, the NRC concluded that the CAVI RSO willfully (in careless disregard) directed the shipment of the sources from NC Systems and the purchase and receipt of the sources by CAVI. In accordance with the NRC Enforcement Policy, the NRC assessed the violation at SL IV. The violation is cited in the enclosed Notice because it was identified by the NRC.

Based on the inspection, the NRC identified one additional SL IV violation involving the failure by CAVI to perform geometrical variation testing on one cubic centimeter (1 cc) syringes used in the nuclear medicine department, as required by 10 CFR 35.60(b). This violation is cited in the enclosed Notice because it was identified by the NRC.

During our inspection exit meeting on July 10, 2014, you indicated that CAVI has taken the corrective and preventative actions documented in your February 29, 2012 correspondence, including performing geometry testing of the dose calibrator for 1 cc syringes with no concerns noted; and that CAVI is committed to radiation safety and to compliance with NRC regulations and its license conditions. Further, you verbally confirmed on July 10, 2014, that CAVI will take additional corrective and preventative actions to fully address each violation, including:

(1) submitting a notification to the NRC confirming that the original distributor of the sealed sources was informed that the sources were distributed to you from NC Systems and they have updated their records; (2) submitting a license amendment signed by management naming a new RSO, since the prior RSO has discontinued services, and (3) ensuring that future amendment requests are either signed by management or that authority is delegated by management to the RSO to sign the request.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence are already adequately addressed in our records and in your correspondence dated February 29, 2012. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your February 29, 2012, correspondence do 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, 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.

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

/RA/

James W. Clifford, Director
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc: Territory of the Virgin Islands

K. Griffith

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Sincerely,

/RA/

James W. Clifford, Director
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc: Territory of the Virgin Islands

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NOTICE OF VIOLATION

Cardiovascular Associates of the Virgin Islands, PLLC
Christiansted, St. Croix, VI

Docket No. 03037806
License No. 55-31325-01
EA-14-065

During an NRC inspection conducted on February 9, 2012, with continued in-office review thru July 10, 2014, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.65(b) states, in part, that any person authorized by 10 CFR 35.11 for medical use of byproduct material may receive, possess, and use sealed sources not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 10 CFR 32.74 or equivalent Agreement State regulations.

Contrary to the above, in March 2011, CAVI received calibration sources (two cobalt-57 sealed sources) that were shipped on March 3, 2011, from NC Systems, a company that was not authorized to redistribute the sources.

This is a Severity Level IV violation.

- B. 10 CFR 35.12(a) requires that an application for a license amendment must be signed by the licensee's management.

10 CFR 35.2 defines management as the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Contrary to the above, on March 14, 2011, CAVI submitted an application for a license amendment to provide leak testing services to other licensees that was not signed by licensee management. Specifically, the amendment application was signed by the Radiation Safety Officer, who was neither authorized nor delegated to manage, direct, or administer the licensee's activities.

This is a Severity Level IV violation.

- C. 10 CFR 35.60(b) requires, in part, that the licensee shall calibrate the instruments used to measure the activity of unsealed byproduct material in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, as of February 9, 2012, CAVI did not calibrate instrumentation used to measure the activity of unsealed byproduct material in accordance with nationally recognized standards or the manufacturer's instructions.

Specifically, the instrument was not calibrated for geometric independence for one cubic centimeter syringes used in the nuclear medicine department.

This is a Severity Level IV violation (Section 6.3).

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 29th day of August 2014