



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713**

July 19, 2018

William Gunkel, Jr., Radiation Safety Officer
Delaware Cardiovascular Associates
1403 Foulk Road, Suite 101A
Wilmington, DE 19803

**SUBJECT: DELAWARE CARDIOVASCULAR ASSOCIATES, NRC INSPECTION NO.
03034602/2018001 AND NOTICE OF VIOLATION**

Dear Mr. Gunkel:

This letter refers to the inspection conducted on June 26 and 27, 2018 at your Lewes, Ocean View, Bear, and Dover, Delaware facilities. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with 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, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

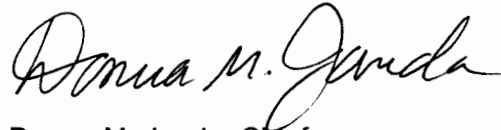
You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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 Web site 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.

If you have any questions regarding this matter, please contact Farrah Gaskins of my staff at (610) 337-5143 or via electronic mail at Farrah.Gaskins@nrc.gov.

Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink that reads "Donna M. Janda". The signature is written in a cursive style with a large, looping initial 'D'.

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03034602
License No. 07-30420-01

Enclosure:
Notice of Violation

cc w/ enclosure
State of Delaware

DELAWARE CARDIOVASCULAR ASSOCIATES, NRC INSPECTION NO. 03034602/2018001
AND NOTICE OF VIOLATION DATED JULY 19, 2018

DISTRIBUTION:
Brice Bickett, RI

DOCUMENT NAME: G:\WBL Documents\WBL Inspection Letter\L07-30420-01.2018001.docx

SUNSI Review Complete: [FGaskins]

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/enc! "E" = Copy w/ attach/enc! "N" = No copy

OFFICE	RI:DNMS	N		N				
NAME	FGaskins		DJanda					
DATE	7/16/18		7/19/18					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Delaware Cardiovascular Associates
Wilmington, DE

Docket No. 03034602
License No. 07-30420-01

During an NRC inspection conducted on June 25 and 26, 2018, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation(s) are listed below:

- A. 10 CFR 20.1802 requires, in part, that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on June 25, 2018, the licensee failed to maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that is not in storage. Specifically, approximately 1mCi of unsealed Technetium 99m, 25mCi of sealed sources containing Cobalt 57 and 224 microcuries of sealed sources containing Cesium 137 was found unattended in an unlocked hotlab area at the Ocean View, DE location.

This is a Severity Level IV violation (Enforcement Policy Section 6.7).

- B. 10 CFR 71.5 requires, in part, that the licensee follows applicable Department of Transportation regulations when offering hazardous material for transport.

49 CFR 172.702(a) requires, in part, that a hazmat employer ensure that each of its hazmat employees are trained in accordance with the requirements.

49 CFR 172.704 requires that the hazmat employee must be trained every 3 years and the training must include: (1) general awareness and familiarization training; (2) function specific training; (3) safety training; and (4) security awareness training.

Contrary to the above the licensee, as of June 25, 2018, the licensee did not ensure each of its hazmat employees were trained in accordance with requirements. Specifically, the Certified Nuclear Technologists have not received hazmat training but offer unused unit doses of licensed materials to be transported back to nuclear pharmacy and offer sealed sources being returned to manufacturer.

This is a Severity Level IV violation (Enforcement Policy Section 6.3)

Pursuant to the provisions of 10 CFR 2.201, Delaware Cardiovascular Associates is hereby required to submit a written statement or explanation 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). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response.

If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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 19th day of July 2018