



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

April 2, 2015

Docket No. 03035150

License No. 47-25478-01

M. Yaser Haffar, M.D.
Cardiovascular Consultants, PLLC
1211 Hospital Drive
Hurricane, WV 25526

**SUBJECT: INSPECTION OF CARDIOVASCULAR CONSULTANTS, PLLC, HURRICANE,
WEST VIRGINIA SITE AND NOTICE OF VIOLATION**

Dear Dr. Haffar:

On February 19, 2015, Mr. Shawn Seeley of this office conducted a safety inspection at the above address of activities authorized by your NRC license. The review of your licensed activities continued in the Region I office until March 26, 2015. 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. Mr. Seeley discussed the results of the inspection with Amy Griffith, Gerry Spears, and you via telephone at the conclusion of the inspection on March 26, 2015.

Based on the results of this inspection, and in accordance with the NRC Enforcement Policy, the NRC has determined that five Severity Level IV violations of NRC requirements occurred. The violations involved the failure to: (1) test the sealed source for leakage at six-month intervals; (2) conduct survey instrument calibrations annually; (3) conduct quarterly linearity checks of the dose calibrator; 4) conduct adequate DOT Hazmat training; and (5) conduct an adequate annual audit of the radiation protection program.

The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC. The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and compliance. Because of the potential for radiation exposure to employees and the public which could result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application.

You are required to respond to this letter and should follow the instruction specified in the enclosed Notice when preparing your response.

During our inspection exit meeting on March 26, 2015, you stated that you had taken corrective and preventative actions to address each violation and that you are committed to radiation safety and to compliance with NRC regulations and licensed conditions. Specifically, you indicated that:

1. You have programmed reminders into the Centrex system utilized in nuclear medicine to prompt the technician when required items are due; and
2. You are committed to ensuring compliance with the regulations and will take prompt corrective action to prevent recurrence of the violations.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, 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.htm>. 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 Shawn Seeley at 610-337-5102 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 West Virginia

1. You have programmed reminders into the Centrex system utilized in nuclear medicine to prompt the technician when required items are due; and
2. You are committed to ensuring compliance with the regulations and will take prompt corrective action to prevent recurrence of the violations.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, 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.htm>. 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 Shawn Seeley at 610-337-5102 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 West Virginia

Distribution: B. Bickett, RI

DOCUMENT NAME: G:\DNMS\WordDocs\Current\Insp Letter\L47-25478-01.2015001.docx

SUNSIReview Complete: SSeeley

ML15096A378

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/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI		
NAME	SSeeley/ss		JDwyer/jd				
DATE	3/27/15		4/2/15				

NOTICE OF VIOLATION

Cardiovascular Consultants, PLLC
Hurricane, WV

Docket No. 03035150
License No. 47-25478-01

During an NRC inspection conducted on February 19, 2015, with continued in-office review until March 26, 2015, five violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.67(b) requires, in part, that a licensee in possession of sealed sources shall test the source for leakage at intervals not to exceed 6 months.

Contrary to the above, as of February 19, 2015, a licensee in possession of sealed sources did not test the sources for leakage at intervals not to exceed 6 months. Specifically, sealed sources were not tested since April 2014, a period of time greater than 6 months.

This is a Severity Level IV violation (Section 6.7)

- B. 10 CFR 35.60(b) requires, in part, that a licensee shall calibrate instruments used to measure the activity of unsealed materials in accordance with nationally recognized standards. Specifically, the nationally recognized standards recommend a quarterly (i.e. every 3 months) frequency for determining the linearity of the instrument.

Contrary to the above, as of February 19, 2015, the licensee did not calibrate the dose calibrator at the required frequency (every 3 months). Specifically, the linearity was not performed between July 2013 and January 2014, and April 2014 and December 2014, both periods of time greater than 3 months.

This is a Severity Level IV violation (Section 6.7)

- C. 10 CFR 35.61(a) requires, in part, that a licensee shall calibrate survey instruments annually.

Contrary to the above, as of February 19, 2015, survey instruments were not calibrated annually. Specifically, the survey instrument utilized by the licensee was not calibrated from December 15, 2012 to April 9, 2014, a period of time greater than annually.

This is a Severity Level IV violation (Section 6.7)

- D. 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(d) requires, in part, that a hazmat employer shall ensure that each hazmat employee is tested on the training subjects covered in 49 CFR 172.704.

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

Contrary to the above, as of February 20, 2015, the licensee did not ensure the hazmat employee training included security awareness training. Specifically, the hazmat employee quiz taken by the CNMT on February 20, 2015, did not address the security awareness component of the required training subjects.

This is a Severity Level IV violation (Section 6.3)

- E. 10 CFR 20.1101 requires, in part, that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, as of February 19, 2015, the licensee had not conducted an adequate review of the radiation program protection program content and implementation. Specifically, the licensee hired an independent consultant to review the radiation protection program content and implementation from information submitted to him. As a result, an inadequate audit was conducted and the inattention to detail resulted in the citation of four violations.

This is a Severity Level IV violation (Section 6.3)

Pursuant to the provisions of 10 CFR 2.201, Cardiovascular Consultants, PLLC, 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 2nd day of April 2015