



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

March 14, 2013

Docket No. 03037413

License No. 47-31223-01

Scott P. Duffy, M.D.
President & Radiation Safety Officer
Kanawha Valley Heart Specialists, Inc.
dba West Virginia Heart and Vascular Institute
4610 Kanawha Avenue, S.W., 2nd Floor
South Charleston, WV 25309

SUBJECT: NRC INSPECTION REPORT NO. 03037413/2013001, KANAWHA VALLEY HEART SPECIALISTS, INC., DBA WEST VIRGINIA HEART AND VASCULAR INSTITUTE, SOUTH CHARLESTON, WEST VIRGINIA AND NOTICE OF VIOLATION

Dear Dr. Duffy:

On February 28, 2013, Robin Elliott of this office conducted a safety inspection at the above address of activities authorized by your NRC license. 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. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection, and in accordance with the NRC Enforcement Policy, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation involved the failure to control and maintain constant surveillance of licensed material that is in a controlled area and that is not in storage.

The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

At the conclusion of the on-site inspection on February 28, 2013, you indicated that you would purchase a combination locking device for the hot lab door and committed to locking the door when the room is not attended. During the exit meeting on March 6, 2013, you stated that you will have the installation of the lock completed within 30 days and that Kanawha Valley Heart Specialists, Inc. is committed to radiation safety and to compliance with NRC regulations and licensed conditions.

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

S. Duffy, M.D.

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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/regulatory/enforcement/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 Robin Elliott at (610) 337-5076 if you have any questions regarding this matter.

Sincerely,

Original signed by Penny Lanzisera for
James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
State of West Virginia

S. Duffy, M.D.

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Enclosure:
Notice of Violation

cc:
State of West Virginia

Distribution:

D. J. Holody, RI

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI		
NAME	RElliott/re		JDwyer/jd			
DATE	3/13/13		3/14/13			

S. Duffy, M.D.

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OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Kanawha Valley Heart Specialists, Inc.
South Charleston, WV

Docket No. 03037413
License No. 47-31223-01

During an NRC inspection conducted on February 28, 2013, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

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

Contrary to the above, on February 28, 2013, the licensee did not control and maintain constant surveillance of licensed material that was in a controlled area and that was not in storage. Specifically, 100 mCi of Tc-99m was left unattended in an unlocked hot lab while the nuclear medicine technologist attended to a patient in the injection room.

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

The NRC has concluded that information regarding the reason for the violation, 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 14 day of March 2013