



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

February 14, 2024

Joseph Dibacco
Director of Radiology
Davis Medical Center
P.O. Box 1484
Elkins, WV 26241-1484

**SUBJECT: DAVIS MEDICAL CENTER - NRC INSPECTION NO. 030-29484/2023-001 AND
NOTICE OF VIOLATION**

Dear Dr. Patrick Alex Brown:

This letter refers to the inspection conducted on December 20, 2023, at your facility in Elkins, West Virginia., with an in-office review through February 2, 2024. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. The preliminary inspection findings were discussed with you and your staff following the conclusion of the onsite portion of the inspection on December 20, 2023. A final exit briefing was conducted telephonically with you, Patrick Brown, M.D, Radiation Safety Officer, Edward Phillips, Chief Legal Officer and Corporate Secretary, Vandalia Health North, Apryl Strother, System Director Corporate Compliance and Privacy, and Kelly Stoneberg, consultant physicist, on February 2, 2024.

Based on the results of this inspection, the NRC has determined that three 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. The violations involved the failures to: (1) request and receive written consent by the NRC prior to an indirect Change-of-Control, (2) account for occupational exposure received by staff while working at facilities other than Davis Medical Center, and (3) adequately control and maintain constant surveillance of licensed material.

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's 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 " Agency Rules of Practice and Procedure," a copy of this letter 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 Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Jason vonEhr of my staff at (610) 337-5256 or via electronic mail at Jason.vonEhr@nrc.gov.

Thank you for your cooperation.

Sincerely,

/for/

Anne DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-29484
License No. 47-24864-01

Enclosure:
Notice of Violation

cc w/ enclosure
Patrick Brown, M.D., Radiation Safety Officer
Edward Phillips, Chief Legal Officer and Corporate Secretary, Vandalia Health North
Apryl Strother, System Director Corporate Compliance and Privacy
State of West Virginia

DAVIS MEDICAL CENTER - NRC INSPECTION NO. 030-29484/2023-001 AND NOTICE OF VIOLATION DATED FEBRUARY 14, 2024

DISTRIBUTION:

None

DOCUMENT NAME: <https://usnrc.sharepoint.com/teams/Region-I-MLA/Inspection%20Reports/Inspection%20Documentation%20-%20Draft/R47-24864-01.2023-001.NOV.docx>

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OFFICE	RI:DRSS	RI:DRSS	RI:DRSS		
NAME	Michael Wutkowski	Jason vonEhr	Anne DeFrancisco (MF for)		
DATE	02/12/2024	02/12/2024	02/14/24		

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Davis Medical Center
Elkins, West Virginia

Docket No. 030-29484
License No. 47-24864-01

During an NRC inspection conducted December 20, 2023, with an in-office review through February 2, 2024, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 30.34(b)(1) requires that no license issued or granted pursuant to the regulations in 10 CFR Part 30 and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

Contrary to the above, on December 1, 2023, the subject NRC license was transferred either voluntarily or involuntarily, directly or indirectly, through transfer of control to another person without the Commission giving its consent in writing. Specifically, the licensee was indirectly transferred through a change of control to Monongalia Health System, Inc., doing-business-as Vandalia Health North, a subsidiary of Vandalia Health, Inc., without notifying and without receiving consent in writing from the Commission.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d.7)

- B. 10 CFR 20.1201(f) requires that the licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Contrary to the above, in three instances from at least March 18, 2022, through December 20, 2023, the licensee failed to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Specifically, for three individuals who performed licensed activities under the NRC license, the licensee failed to assess all the occupational dose received while the individuals continued their employment by other organizations for which the individuals had duties that involved exposure to radiation.

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

- C. 10 CFR 20.1802 requires that the licensee shall 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 December 20, 2023, the licensee failed to maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. Specifically, licensee staff on two occasions attempted to leave the controlled area and would have been unable to maintain constant surveillance of unused doses of technetium-99m, totaling approximately 144 millicuries.

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

For Violation A: Pursuant to the provisions of 10 CFR 2.201, Davis Medical Center 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 Violation A: (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 or was 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.

Davis Medical Center took prompt and comprehensive actions to address Violations B and C. These actions included: (1) identifying and contacting the facilities that Davis Medical Center's staff had parallel employment at and received occupational exposure to radiation from in order to share and receive occupational exposure information, (2) aggregating this exposure information into the associated staff's occupational exposure records maintained by Davis Medical Center, (3) creating an action to occur at least annually to identify, share, and receive occupational exposure information on a continuing basis into the future, (4) modifying the doors to the radiology hot lab to lock automatically upon closure, open using a technologists' Identification Badge, and installing an auto-closing mechanism to prevent the door being left ajar, and (5) providing timely remedial training to all staff regarding the NRC's regulations for the security and control of licensed material both in use and in storage. These actions were communicated to the NRC during the in-office review and deemed adequate to restore compliance and provide a basis for confidence that the licensee could reasonably prevent recurrence of Violations B and C described above. No response is required for Violations B and C unless the description above does not reflect Davis Medical Center's position or perspective on these matters.

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 or proprietary information so that it can be made publicly available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that

Notice of Violation
Davis Medical Center

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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 14th day of February 2024