



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2056 WESTINGS AVENUE, SUITE 400  
NAPERVILLE, IL 60563-2657

June 25, 2025

EA-24-108  
EAF-RIII-2025-0008  
EN 57069  
NMED No. 240128

Stephen Andrew Vartanian, M.D.  
Vartanian Medical, PLLC  
32255 Northwestern Hwy.  
Ste.135  
Farmington Hills, MI 48334

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO.  
03039334/2024002 (DRSS) - VARTANIAN MEDICAL, PLLC

Dear Dr. Vartanian:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on April 16, 2024, at your Farmington Hills, Michigan, clinic with continued in-office review through March 21, 2025. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that occurred on April 9, 2024; your staff reported this medical event to the NRC on the same day. The medical event involved an underdose to the treatment site utilizing yttrium-90 (Y-90) microspheres within the TheraSphere™ brachytherapy system. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you during an exit meeting on March 21, 2025. Inspection Report No. 03039334/2024002 (DRSS) was issued on April 16, 2025, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML25042A576. ADAMS is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference, by attending an alternative dispute resolution (ADR) session, or by providing a written response before we made our final enforcement decision. In a letter dated May 15, 2025, (ML25142A198) you provided a response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated May 15, 2025, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

The violations involved your failure to (A) have written procedures that verified that each Y-90 administration was administered in accordance with the treatment plan and written directive and addressed determining if a medical event occurred as required by 10 CFR 35.41(b)(2) and 35.41(b)(5); (B) provide notification of a medical event to the referring physician within 24 hours after its discovery as required by 10 CFR 35.3045(e); and (C) have a written directive that was dated and signed by the authorized user before the administration as required by 10 CFR 35.40(a).

The failure to have written procedures that verify administrations are administered in accordance with the treatment plan and written directive that address determining if a medical event occurred is a significant safety concern as it could result in failing to identify situations where an incorrect dose was delivered to a patient. The failure to provide notification of a medical event to the referring physician within 24 hours is a significant safety concern as it could delay assessment or treatment of potential adverse health effects as a result of a medical event. Therefore, violations A and B have been categorized in accordance with the NRC Enforcement Policy at Severity Level III. Violation C has been categorized at Severity Level IV.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9,000 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. In your May 15, 2025, letter you described your corrective actions for the apparent violations.

For violation A, your corrective actions included: 1) reviewing and revising your internal protocol for Y-90 treatments and developing procedures to ensure verification of the treatment site and dosage prior to administration, providing step-by-step guidance for verifying patient identity and checking vial activity, and establishing clear criteria for identifying and documenting medical events; 2) developing annual staff training on NRC compliance and internal protocols; 3) requiring verification by two staff members, including a physician; 4) performing quarterly audits of Y-90 cases to ensure procedural compliance. You stated these actions were completed by August 1, 2024.

For violation B, your corrective actions included: 1) immediately contacting the referring physician on April 16, 2024; 2) creating a Medical Event Response Standard Operating Procedure (SOP), which includes a 24-hour timeline checklist and staff notification responsibilities; and 3) locating this SOP in the nuclear medicine suite and integrating it into staff orientation and retraining modules. You stated these actions were completed by April 16, 2024.

For violation C, your corrective actions included: 1) the physician retroactively signing and dating the April 9, 2024, written directive; 2) revising the written directive form to ensure the signature and date fields are clearly indicated and required before administration; 3) implementing a review system that prevents proceeding with treatment unless the directive is completed and signed; and 4) training staff to check for signed directives as a standard safety step. You stated these actions were completed by April 22, 2024.

Based on these described actions, the NRC has determined that credit is warranted for *Corrective Action* in accordance with the civil penalty assessment process. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of these Severity Level III violations constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03039334/2024002 (DRSS) and your letter dated May 15, 2025. Therefore, you are not required to respond to this letter unless the description therein 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,



Signed by Giessner, Jack  
on 06/25/25

John B. Giessner  
Regional Administrator

Docket No. 030-39334  
License No. 21-35697-01

Enclosure: Notice of Violation

cc w/encl: Jeffrey H. Margolis, M.D.,  
State of Michigan

Letter to S. Vartanian from J. Giessner dated June 25, 2025.

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO. 03039334/2024002 (DRSS) - VARTANIAN MEDICAL, PLLC

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## NOTICE OF VIOLATION

Vartanian Medical, PLLC  
Farmington Hills, Michigan

Docket No. 030-39334  
License No. 21-35697-01  
EA-24-108  
EAF-RIII-2025-0008

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on April 16, 2024, with continued in-office review through March 21, 2025, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10 of the Code of Federal Regulations (10 CFR) 35.41(a) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Title 10 CFR 35.41(b)(2) states, in part, that the written procedures required by 10 CFR 35.41(a) must address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Title 10 CFR 35.41(b)(5) states, in part, that the written procedures required by 10 CFR 35.41(a) must address determining if a medical event, as defined in 10 CFR 35.3045, has occurred.

Contrary to the above, prior to April 16, 2024, the licensee failed to have written procedures that provided high confidence that each yttrium-90 administration was verified to be administered in accordance with the treatment plan and written directive, and addressed determining if a medical event, as defined in 10 CFR 35.3045, had occurred. Specifically, the licensee used a treatment worksheet and checklist, provided by the device manufacturer, which failed to include steps for verifying whether the administration was in accordance with the treatment plan and written directive, and determining whether a medical event occurred.

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

- B. Title 10 CFR 35.3045(e) requires, in part, that the licensee to provide notification of a [medical] event to the referring physician no later than 24 hours after its discovery.

Contrary to the above, on April 9, 2024, the licensee became aware that a medical event had occurred, and the licensee did not provide notification of the event to the referring physician until April 16, 2024. This period was greater than 24 hours after its discovery.

This is a Severity Level III violation (Enforcement Policy Example 6.9).

- C. Title 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

Enclosure

Contrary to the above, on April 9, 2024, the licensee did not have a written directive that was dated and signed by an authorized user before the administration of a therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material. Specifically, on April 9, 2024, the licensee administered a 4.5 gigabecquerel therapeutic dosage of yttrium-90 microspheres and did not have a written directive that was dated and signed by the authorized user before the administration of this therapeutic dosage.

This is a Severity Level IV violation (Enforcement Policy Example 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 was achieved, is already adequately addressed on the docket in Inspection Report No. 03039334/2024002 (DRSS) and the licensee's letter dated May 15, 2025. However, the licensee is required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect the licensee's corrective actions or position. In that case, or if the licensee chooses to respond, the licensee should clearly mark its response as a "Reply to a Notice of Violation, (EA-24-108; EAF-RIII-2025-0008)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2056 Westings Avenue, Naperville, IL 60563 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If the licensee contests this enforcement action, the licensee should also provide a copy of its response, with the basis for its denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If the licensee chooses to respond, the licensee's response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, the licensee may be required to post this Notice within two working days of receipt.

Dated this day of 25<sup>th</sup> day of June 2025.