



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

November 26, 2025

EAF-RIII-2025-0111

Tigran Sinanian  
Business Administration  
Manufacturing Manager  
PETNET Solutions, Inc.  
810 Innovation Dr.  
Knoxville, TN 37932

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NOS.  
03038156/2025001 (DRSS) AND 03038158/2025001 (DRSS) – PETNET  
SOLUTIONS, INC.

Dear Tigran Sinanian:

This letter refers to the inspection conducted on March 13, 2025, at your co-located facilities in Indianapolis, Indiana, with continued in-office review through July 15, 2025. The purpose of the inspection was to review activities performed under your U.S. Nuclear Regulatory Commission (NRC) licenses to ensure that activities were being performed in accordance with NRC requirements. The purpose of the in-office review was to review information that was made available after the onsite inspection. During the inspection, three apparent violations of NRC requirements were identified. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with your staff during an exit meeting on July 15, 2025. Inspection Report Nos. 03038156/2025001 (DRSS) and 03038158/2025001 (DRSS) were issued on August 1, 2025, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML25198A115. 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 or by providing a written response before we made our final enforcement decision. In a letter dated August 21, 2025, (non-public) 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 August 21, 2025, the NRC has determined that three violations of NRC requirements occurred. While all three violations were associated with activities conducted under your radiopharmacy license (NRC License No. 41-32720-02MD), only one of the violations was also associated with activities conducted under your cyclotron license (NRC License No. 41-32720-01). These violations are cited in the enclosed Notices of Violation (Notices), and the circumstances surrounding them are described in detail in the subject inspection report.

One of these violations involved the failure to secure from unauthorized access licensed materials that were stored in a controlled area as required by Title 10 of the *Code of Federal Regulations* 20.1801. The failure to properly secure access to licensed material is of significant concern to the NRC because of the potential for unauthorized individuals to gain access or control of the radioactive material and result in misuse of material or unnecessary exposure to radiation. Because the areas that were left unsecured provided access to licensed material possessed under both your radiopharmacy license and your cyclotron license, this violation applies to each license, and the aggregate quantity of unsecured licensed material possessed under both licenses was used to assess the significance of the violation. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9000 is considered for a Severity Level III violation. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

Because your facility has not been the subject of escalated enforcement actions within the last two years or 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. During the inspection, to restore compliance, you closed and secured the doors and retrained staff on the requirements to control radioactive material. In your response dated August 21, 2025, you described additional actions you have taken or plan to take to avoid future violations including: (1) adding a doorbell to the entry door so that the carrier could notify staff of their arrival, (2) installing a supplementary air conditioning unit to eliminate the need for the doors to be propped open, (3) installing a coded lock on the door between the cyclotron vault storage area and the mechanical room, and (4) submitting a license amendment request to reclassify the mechanical room to an unrestricted area to allow access to this area by non-licensee staff when necessary.

Therefore, to encourage prompt identification and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Acting 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 this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

Two other violations are also cited in the enclosed Notice associated with the radiopharmacy and were determined to be Severity Level IV. These violations involved the failure to (1) ensure by examination or appropriate tests that the non-fixed contamination level on shipping packages was within allowable limits in accordance with 10 CFR 71.5(a) and 49 CFR 173.475(i) and (2) conduct your program in accordance with the statements, representation, and procedures contained in your license application associated with monitoring clothing upon exiting restricted areas. These violations were also evaluated in accordance with the NRC Enforcement Policy and are cited in the Notice because they were identified by the inspector.

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 will be achieved is already adequately addressed on the docket in Inspection Report Nos. 03038156/2025001 (DRSS) and 03038158/2025001 (DRSS) and your letter dated August 21, 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 Notices.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures, and your response if you choose to provide one 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, any response you provide 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/>.

If you have any questions concerning this matter, please contact Diana Betancourt-Roldan, Enforcement and Investigations Officer, at 630-810-4373.

Sincerely,



Signed by Giessner, Jack  
on 11/26/25

John B. Giessner  
Regional Administrator

Docket Nos. 030-38156 and 030-38158  
License Nos. 41-32720-01 and 41-32720-02MD

Enclosures: Notice of Violation (NRC License  
No. 41-32720-01 (cyclotron))  
Notice of Violation (NRC License  
No. 41-32720-02MD (radiopharmacy))

cc (w/encl): Heather McCully, RPh., RSO  
State of Indiana  
State of Tennessee

Letter to T. Sinanian from J Giessner dated November 26, 2025.

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NOS.  
03038156/2025001 (DRSS) AND 03038158/2025001 (DRSS) – PETNET  
SOLUTIONS, INC.

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DATE	11/19/2025		11/19/2025		11/19/2025		11/24/2025	
OFFICE	RIII-EICS		RIII-ORA					
NAME	DBetancourt- Roldan		JGiessner					
DATE	11/25/2025		11/26/2025					

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## NOTICE OF VIOLATION

PETNET Solutions, Inc. (cyclotron)  
Indianapolis, Indiana  
EAF-RIII-2025-0111

Docket No. 030-38156  
License No. 41-32720-01

During an NRC inspection conducted on March 13, 2025, with continued in-office review through July 15, 2025, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

Title 10 of the *Code of Federal Regulations* (CFR) 20.1801 requires that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled areas.

Contrary to the above, on March 13, 2025, the licensee failed to secure from unauthorized removal or access licensed materials that were stored in a controlled area. Specifically, the licensee propped open the entry door to their facility as well as the emergency exit door which allowed access to 3.6 mCi of hydrogen-3, 1.1 mCi of cobalt-56, 1.8 mCi of cobalt-57, 3.7 mCi of manganese-54, microcurie amounts of other radionuclides, and an unquantified amount of activation products within equipment and facility shielding that was being stored in a controlled area.

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

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 Nos. 03038156/2025001 (DRSS) and 03038158/2025001 (DRSS) and the letter from the Licensee dated August 21, 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, (EAF-RIII-2025-0111)," 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, Suite 400, Naperville, IL 60563 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If the Licensee chooses to respond, the 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 26 day of November 2025.

## NOTICE OF VIOLATION

PETNET Solutions, Inc. (radiopharmacy)  
Indianapolis, Indiana  
EAF-RIII-2025-0111

Docket No. 030-38158  
License No. 41-32720-02MD

During an NRC inspection conducted on March 13, 2025, with continued in-office review through July 15, 2025, 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* (CFR) 20.1801 requires that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled areas.

Contrary to the above, on March 13, 2025, the licensee failed to secure from unauthorized removal or access licensed materials that were stored in a controlled area. Specifically, the licensee propped open the entry door to their facility as well as the emergency exit which allowed access to 985 millicuries (mCi) of fluorine-18 (F-18) that was being stored in a controlled area.

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

- B. Title 10 CFR 71.5(a) requires, in part, that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, shall comply with the applicable requirements of the Department of Transportation in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

Title 49 CFR 173.475(i) requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror must ensure by examination or appropriate tests, that the external radiation and contamination levels are within the allowable limits in 49 CFR Subchapter C.

Contrary to the above, on March 13, 2025, the licensee did not ensure by examination or appropriate tests that the non-fixed contamination level was within the allowable limits in 49 CFR Subchapter C prior to offering the packages for shipment. Specifically, three packages were not surveyed for non-fixed contamination prior to being given to the carrier for transport to customers' facilities.

This is a Severity Level IV violation (Section 6.3).

- C. License Condition 23 of License No. 41-32720-02MD, dated May 14, 2024, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated August 28, 2020.

Item 10 of the application dated August 28, 2020, states, in part, that the licensee will employ the following rules for the safe use of radioactive materials: monitor hands, feet, and clothing upon exiting the restricted areas.

Contrary to the above, on March 13, 2025, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the application dated August 28, 2020. Specifically, multiple individuals using radioactive materials failed to monitor their hands, feet, and clothing upon exiting the restricted areas. Furthermore, additional individuals using radioactive materials failed to monitor their clothing upon exiting the restricted areas.

This is a Severity Level IV violation (Section 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 Nos. 03038156/2025001 (DRSS) and 03038158/2025001 (DRSS) and the letter from the Licensee dated August 21, 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, (EAF-RIII-2025-0111)," 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, Suite 400, Naperville, IL 60563 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If the Licensee chooses to respond, the 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 26 day of November 2025.