



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

December 16, 2014

Ms. April Chance, CHP
Senior Manager of Radiation Protection/Environmental
Health & Safety
Molecular Technologies Division of Siemens
Molecular Imaging
(PETNET, Cyclotrons and Sources)
810 Innovation Drive
Knoxville, TN 37932

Dear Ms. Chance:

Enclosed is Amendment Number 05 to your NRC Material License No. 41-32720-03 in accordance with your request.

This amendment incorporates procedures and controls you have established to reduce the amount of fluorine-18 gas effluent that is released from cyclotron-production activities at the St. Louis location. The amendment also incorporates modifications made to the access controls for the garden area adjacent to Saint Louis University Hospital to prevent members of the public from entering the garden area where the fluorine-18 gas effluent is released.

Please note that License Condition Numbers 19 and 20 have been added to your license. These conditions were added to your license because you did not provide a valid technical justification for the inconsistency and disproportionality in the detector response data versus the discharge increments generated by the Lab Impex software for the fluorine-18 gas effluent. Several examples of inconsistencies were pointed out to you and your staff on numerous occasions, including during a conference call that was conducted on July 29, 2014. Mr. Kevin Null of my staff discussed the addition of these license conditions with Mr. Ramon Davila of your staff on October 31, 2014.

The NRC determined that your St. Louis facility would exceed the 10 millirem annual constraint limit specified in Title 10 of the *Code of Federal Regulations* (CFR) Part 20, Section 20.1101(d) for a release of fluorine-18 gas effluent that exceeds 1200 microcuries per day or 300 millicuries annually. Due to the uncertainty in the reliability of the software generated data, License Condition Number 19 was added to your license which requires PETNET Solutions, Inc. to perform confirmatory calculations to verify the software generated results whenever the effluent monitoring system identifies a daily release greater than 1200 microcuries of fluorine-18 gas effluent. In addition, License Condition Number 20 was added to your license which requires PETNET Solutions, Inc. to limit the annual fluorine-18 gas effluent to less than 300 millicuries. These limitations provide reasonable assurance to the NRC that PETNET Solutions, Inc. will not exceed the 10 millirem annual constraint limit specified in 20.1101(d).

During a telephone conversation on October 31, 2014, Mr. Davila stated to Mr. Null that PETNET Solutions, Inc. plans to cease licensed activities at the St. Louis location by the end of January 2015. Based on that discussion and the notification requirements specified in 10 CFR Part 30, it is our understanding that PETNET Solutions, Inc. will submit a letter to the NRC which outlines plans to cease operations and include a projected timeline for license termination.

Finally, as a result of lengthy reviews of the software generated release discharge values and the inconsistencies that were noted between those values and the detector response, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation concerned the licensee's failure to calibrate its Lab Impex Systems PG-10 positron gas detector, an instrument that is used for quantitative radiation measurements, as required by Title 10 CFR Part 20.1501(c). The violation is cited in the enclosed Notice of Violation (Notice).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC's Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

A copy of this violation will be provided to the Materials Inspection Branch for follow-up at other PETNET Solutions, Inc. facilities who release radioactive gas effluent resulting from cyclotron-production activities. Consequently, we encourage you to address this potential generic issue at your other facilities and take prompt corrective action.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:
 - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the mailing address listed on the license changes.
3. In accordance with 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license; or
 - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
4. Request and obtain a license amendment before you:
 - a. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - b. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - c. Change ownership of your organization.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

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's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's 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 publicly available without redaction.

A. Chance

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Please contact me at (630) 829-9868 or Mr. Null of my staff at (630) 829-9854 if you have any questions regarding the information discussed above.

Sincerely,

/RA/

Patricia J. Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 41-32720-03
Docket No. 030-38230

Enclosures:

1. Notice of Violation
2. Amendment No. 05 to License No. 41-32720-03

A. Chance

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DATE	12/11/14		12/16/14				

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NOTICE OF VIOLATION

PETNET Solutions, Inc.
Knoxville, Tennessee

License No. 41-32720-03
Docket No. 030-38230

During a U.S. Nuclear Regulatory Commission (NRC) review of a license amendment request dated March 29, 2013, and supporting documents submitted through October 3, 2014, and a telephone conversation on October 31, 2014, with Mr. Ramon Davila, Regional Health Physicist, Siemens MI/PETNET Solutions, Inc., a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20.1501(c) requires that the licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

Contrary to the above, as of October 31, 2014, the licensee failed to ensure that an instrument that was used for quantitative radiation measurements was calibrated periodically for the radiation measured. Specifically, the licensee failed to calibrate its Lab Impex Systems PG-10 positron gas detector, an instrument that was used for quantitative radiation measurements of fluorine-18 air effluent released from cyclotron-production activities conducted at 3635 Vista Avenue, Saint Louis, Missouri, under the NRC license.

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

Pursuant to the provisions of CFR 2.201, PETNET Solutions, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, 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: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously 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.

Enclosure 1

Notice of Violation

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Your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's 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.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 16th day of December, 2014.