

## UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III

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

March 30, 2015

EA-15-019

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

SUBJECT: RESPONSE TO DISPUTED NOTICE OF VIOLATION DATED DECEMBER 16, 2014 (NRC LICENSE NO. 41-32720-03; DOCKET NO. 030-38230) – PETNET SOLUTIONS, INC.

Dear Ms. Chance:

This refers to your letters dated January 23, 2015, (ML15040A047) and February 4, 2015, (ML15041A572) submitted in response to the U.S. Nuclear Regulatory Commission (NRC) Notice of Violation (Notice) dated December 16, 2014, (ML14350B163). These documents are available in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <u>http://www.nrc.gov/reading-rm/adams.html</u>, at the listed accession numbers.

The Notice contained one Severity Level IV violation of NRC requirements associated with the calibration of the air effluent monitoring system used at the PETNET cyclotron facility located in Saint Louis, Missouri. Specifically, the Notice documented that the Lab Impex Systems PG-10 Positron Gas Detector used for quantitative measurements of fluorine-18 air effluents was not periodically calibrated for the radiation measured, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 20.1501(c). In your February 4, 2015 letter, you took issue with the NRC's assessment of your calibration methods and contested the issuance of the violation. The letter included two attachments to support your position for the NRC to consider. Attachment A entitled "PG-10 Cs-137 Calibration Check" and Attachment B entitled "PG-10 Positron Gas Detector Calibration Data and Check Source Comparison."

The NRC letter dated February 20, 2015 (ML15054A353) acknowledged receipt of your letters responding to the Notice and advised that the NRC would evaluate the information provided in those letters and inform you of the results of our review by separate correspondence. Consistent with our process for evaluating disputed violations, the NRC assigned an independent member of the NRC staff to perform an evaluation. That person did not report to the same supervisory chain as those involved in the violation and was independent of the original enforcement determination. In order to fully understand your position, the independent

## A. Chance

evaluator reviewed the violation, the two letters submitted in response to the Notice, including associated attachments, and consulted various industry technical documents related to continuously monitoring radioactivity in effluents. The evaluator also contacted Mr. Roger Maroney of your health physics organization on February 26, 2015, to obtain clarifying information regarding the attachments submitted with your February 4, 2015 letter. Mr. Maroney subsequently provided additional information to our office electronically which described the Lab Impex Systems effluent monitor features and specifications (ML15065A186). That information was also reviewed as part of our independent assessment.

The NRC's independent review concluded that the violation cited in the Notice was valid in that the Lab Impex Systems PG-10 Positron Gas detector used at the Saint Louis, Missouri facility was not periodically calibrated for the radiation measured as required by 10 CFR 20.1501(c). The enclosure to this letter provides the basis for this conclusion.

We understand that the PETNET Solutions facility in Saint Louis, Missouri ceased NRC licensed activities as indicated in your letter to the NRC dated February 27, 2015, (ML15061A430). We understand that you plan to terminate NRC License No. 41-32720-03 and submit a decommissioning plan. Given that licensed activities have ceased and will not resume at this facility, corrective actions for the violation are no longer relevant.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC's Public Document Room and in ADAMS.

Sincerely,

/RA/

Patrick L. Louden Acting Deputy Regional Administrator

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

Enclosure: Evaluation of Disputed Violation

## A. Chance

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

Enclosure: **Evaluation of Disputed Violation** 

#### **DISTRIBUTION w/encl:** See next page

#### ADAMS Accession Number: ML15090A299

## **\*SEE PREVIOUS CONCURRENCE**

DOCUMENT NAM	1E: PETNET Contested Viol F	Respo	nse Letter.docx					
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DATE	03/30/15		03/27/15		03/30/15		03/30/15	

#### OFFICIAL RECORD COPY

<sup>1</sup> OE concurrence provided via email from Kerstun Norman on March 27, 2015

Letter to April Chance from Darrell J. Roberts dated March 30, 2015.

SUBJECT: RESPONSE TO DISPUTED NOTICE OF VIOLATION DATED DECEMBER 16, 2014 (NRC LICENSE NO. 41-32720-03; DOCKET NO. 030-38230) – PETNET SOLUTIONS, INC.

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# **EVALUATION OF DISPUTED VIOLATION**

## Violation

Title 10 of the *Code of Federal Regulations* (CFR) Part 20.1501(c) requires that the licensee 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 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.

## Licensee Response

The licensee disagreed with the U.S. Nuclear Regulatory Commission's (NRC's) determination that the Lab Impex PG-10 Positron Gas Detector was not calibrated in accordance with regulatory requirements and the violation was contested. The licensee indicated in both letters that responded to the violation that they followed the manufacturer's recommendations and adhered to the calibration instructions "PG-10 Cs-137 Calibration Check," submitted in the licensee's application dated September 30, 2009. The calibration check document was provided in the February 4, 2015, letter labeled as Attachment A. The licensee also provided (as Attachment B) the calibration methodology provided by the manufacturer. The licensee contended that the methodology described in Attachment B provided adequate technical data and correlation between a laboratory gas calibration and the cesium-137 (gamma) disc source calibration check to satisfy 10 CFR 20.1501(c) requirements.

## NRC Staff's Review

The NRC independent evaluator reviewed the information submitted in the licensee's two letters responding to the Notice of Violation, including two attachments that provided the technical basis for the calibration of the effluent monitoring system used at the facility. Information submitted electronically by a member of the licensee's health physics organization to the NRC on February 26, 2015 (ML15065A186) was also reviewed. Additionally, various U.S. nuclear industry endorsed documents related to continuously monitoring radioactivity in effluents were reviewed to assess the calibration methodology used at the licensee's facility. These documents included NRC Regulatory Guides and Health Physics Positions that set forth acceptable means of meeting regulatory requirements.

Industry information applied by the independent evaluator consisted of:

- American National Standards Institute (ANSI) document (ANSI N13.10-1974 and ANSI N42.18-2004), Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents.
- NRC Regulatory Guide 4.15, Revisions 1 & 2, Quality Assurance for Radiological Monitoring Programs – Effluent Streams and the Environment.

- NRC Regulatory Guide 1.21, Revisions 1 & 2, Measuring, Evaluating and Reporting Radioactivity in Solid Wastes and Releases of Radioactive Material in Liquid and Gaseous Effluents from Light Water Cooled Nuclear Power Plants.
- NRC Health Physics Positions Database (NUREG/CR-5569, Revision 1), HPPOS # 040, Effluent Radiation Monitor Calibrations.
- NRC Information Notice 2013-13, Deficiencies with Effluent Radiation Monitoring System Instrumentation.

10 CFR 20.1501(c) requires that the instrument be periodically calibrated "for the radiation measured." The aforementioned ANSI Standards specify that a thorough "primary" calibration that encompasses the entire system be performed after the system has been installed using a radionuclide of known concentration(s) that permits calibrating the range of energy and rate capabilities intended for the system. As provided in the ANSI standards, traceability to the National Bureau of Standards shall be maintained for the radionuclides used.

The evaluator concluded that neither the initial calibration of the Lab Impex System PG-10 Positron Gas Detector installed at the Saint Louis facility nor any of the subsequent periodic functional response checks (i.e., recalibrations) was adequate to meet 10 CFR 20.1501(c) requirements because:

- (1) The instrument was not calibrated for the radiation measured following installation or during periodic recalibrations. The instrument directly measures the positron (beta) emission of fluorine-18 air effluent released to the environment. The "calibrations" performed by the licensee used a static cesium-137 (gamma) disc source checked at a single point based on a laboratory correlation.
- (2) The calibration methodology described in Attachments A and B to the licensee's February 4, 2015 letter did not meet applicable industry standards as a "primary" calibration. In particular, a calibration was not performed of the installed system (in-situ) using a gas standard of known concentration traceable to the National Bureau of Standards (or equivalent) over the range of effluent rates discharged from the facility.

The evaluator found that the monitoring system's response to air effluents from positron (beta) radiation was never determined after the system was installed at the Saint Louis facility. Also, while the licensee's technical documents described the equivalent of primary and secondary calibrations (defined in the aforementioned industry standards), the effluent monitoring system at the Saint Louis facility never underwent a primary calibration after it was installed. Instead, production detector responses to a gas source with a pedigree not traceable to the National Bureau of Standards (NBS)/National Institute for Standards and Technology (NIST) were evaluated by the device manufacturer in a laboratory setting. As part of that laboratory analyses, a single point correlation to a secondary gamma emitting sealed source was determined for the production detectors. The laboratory derived correlation was subsequently applied at the licensee's Saint Louis facility to check monitor response. The licensee contended that the laboratory evaluation together with the single point correlation to a gamma emitting radionuclide comprised the required calibration.

NRC Health Physics Position (HPPOS-040) specifies that multi-point calibrations are necessary as part of the preoperational acceptance testing (i.e., primary calibration) of effluent monitoring

systems as provided in ANSI N13.10-1974. Regulatory Guides 4.15 and 1.21 endorse ANSI N13.10-1974 and ANSI N42.18-2004, depending on the revision date. Both the 1974 and 2004 ANSI standards and the NRC Regulatory Guides specify that the initial calibration of each measuring system be performed using reference standards certified by a national standards body (NBS or NIST) that permit calibrating the system over its intended range of energy and rate capabilities. Similarly, Regulatory Guide 1.21 indicates that continuous radioactivity monitoring systems should be calibrated against appropriate NIST standards and a relationship established between air effluent concentrations and monitor readings "over the full range of the readout device."

The ANSI standards allow a "secondary calibration" defined as a determination of the response of the system with an applicable source whose effect on the system was established at the time of primary calibration. The secondary calibration is related to a secondary source or method for periodic in-plant recalibration, provided the: (1) source to detector geometry is maintained identical to that established during the primary calibration; and (2) the surface dimensions of the secondary source be the same as the detector window. HPPOS-040 recognizes that secondary (single point) calibrations can be used for periodic recalibrations following the primary calibration.

In summary, the independent evaluator found that the licensee performed functional checks of the effluent monitoring system used at the Saint Louis facility using a correlated response to a gamma emitter as the only "calibration" of the system installed at the site. Consequently, the system was not calibrated for the radiation measured. Moreover, according to the licensee, the monitoring system's response to the secondary gamma emitting source determined during the original installation of the system in 2002 or 2003 was unknown because the documented results were not available. Therefore, the acceptability of the functional check cannot be demonstrated.

Furthermore, the evaluator noted potential flaws with the cesium-137 (gamma) disc source correlation which is used to periodically demonstrate detector response. Specifically, as the laboratory derived (carbon-11) gas calibration conversion factors increase (Figure 6 (labeled Table 6) of the licensee's Reference Document W0215-TD007; Attachment B to letter dated February 4, 2015), the detectors response to the cesium-137 gamma emission plateaued because the detector was relatively insensitive to gamma rays. Although a linear relationship between the detectors gamma response and positron gas response was assumed by the licensee, it was not demonstrated in the data provided. As a result, during periods of increased effluent discharges, the quantification of radioactivity in air effluents from the site could be underestimated.

## NRC Conclusion

After careful consideration of the information gathered, the evaluator concluded that the violation occurred as stated in the Notice of Violation and was properly categorized at Severity Level IV.