

## Null, Kevin

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**From:** Davila Jr, Ramon <ramondavila@siemens.com>  
**Sent:** Tuesday, January 27, 2015 1:45 PM  
**To:** Null, Kevin  
**Subject:** Siemens response to NOV for STL  
**Attachments:** 2015-01-23 Siemens response to NRC NOV dated 12-16-2014\_Final.pdf

Kevin,

The Siemens response to the NRC's notice of violation is attached for your review.

**Ramón Davila, MBA, RRPT** | Regional Health Physicist  
PETNET Solutions | A Siemens Company  
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# PETNET Solutions

January 23, 2015

Mr. Kevin Null  
US Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

**Re:** Reply to a Notice of Violation Docket No. 030-38230 for PETNET St. Louis RAM License 41-32720-03 dated December 16, 2014.

Dear Mr. Null:

Please accept this letter as PETNET's response to the Nuclear Regulatory Commission's (NRC) Notice of Violation (Docket No. 030-38230) dated December 16, 2014 which was received on December 22, 2014.

**NOV #1:**

*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)*

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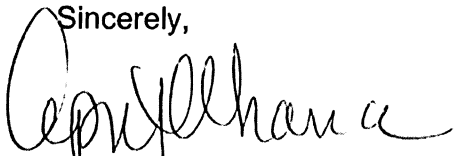
## Response to NOV #1

PETNET has been consistent in conversations regarding calibration of the effluent monitor that a calibration of the system using any positron-emitting radionuclide in gaseous form was not possible at the St. Louis facility due to limitations of the cyclotron. Our alternative was to rely on the manufacturer's calibration documentation that includes the use of a sealed source referenced to gas calibrations performed at a PET facility in the UK as the best available option at that time. This documentation was provided to the NRC. PETNET is continuing to work with the manufacturer to improve the calibration methodology, using a combination of gaseous and sealed sources, as well as Monte Carlo calculations; however we do not expect final results until the end of this year. Therefore PETNET's position is that the system was calibrated per the manufacturer's recommendation in place at the time of installation.

The PETNET St. Louis staff had been performing periodic reference checks with a suitable sealed source as instructed by the manufacturer; however, PETNET also acknowledges that the calibration paperwork is no longer available to document the response of the system to what the source measurement was during the original installation.

Should you require additional information, please feel free to contact me at the number listed below or Ramón Davila at 865-218-3295 or [ramondavila@siemens.com](mailto:ramondavila@siemens.com).

Sincerely,



April Chance, CHP  
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cc: Tigran Sinanian, RPh, BCNP, Sr. Director of Manufacturing Operations  
Ramón Davila, MBA, RRPT, Regional Health Physicist  
John Beyer, RPh, RSO, Regional Operations Director