

# PETNET Solutions

August 8, 2014

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

**Re:** C/N 580329 and PETNET's explanation of fluorine-18 effluent release data and NRC questions about inconsistencies between detector response and discharge increments.

Dear Mr. Null:

Please accept this letter as PETNET's response to the Nuclear Regulatory Commission's (NRC) Conversation Record (580329) dated July 29, 2014 regarding the Lab Impex Stack Monitoring System located at the PETNET St. Louis facility.

## **Concern 1:**

*Clarify the time period(s) when the effluent detection system collects effluent release data. Is effluent release evaluated on a 24 hour clock, or is it only collected when synthesis is being performed? For example, there were periods on April 28 when results were "0" and then there were short durations of time during the early morning when there were positive results.*

## **Response 1**

The radioactive exhaust is monitored continuously. For additional details please see the attached report (Attachment A).

## **Concern 2**

*For the effluent data spreadsheet that you submitted (i.e., April 28, 2014), please include the definition for each column heading, and the units. For example, please define "Raw CPS"; what it means and represents, and where it comes from. As another example, provide the definition of "Background Corrected Dose", and define the units.*

## **Response 2**

Please see attached report (Attachment A) and accompanying spreadsheet titled calculation verification STL April 28 2014 final.xlsx (Attachment B).

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### **Concern 3**

*Please explain discrepancies that appear in the spreadsheet. For example, there are disproportional results in rows 1184 and 1186. The "Raw CPS" values (which we presume to be counts seen by the detector) are essentially the same in both rows, however, the discharge increments vary by a factor of almost 2.*

### **Response 3**

Please see attached report (Attachment A) and accompanying spreadsheet titled calculation verification STL April 28 2014 final.xlsx (Attachment B).

### **Concern 4**

*Identify the columns from the spreadsheet that are used to calculate the discharge value. If there are columns in the spreadsheet that do not factor into the calculation, please identify them and explain why they do not factor into the discharge calculation.*

### **Response 4**

Please see attached report (Attachment A) and accompanying spreadsheet titled calculation verification STL April 28 2014 final.xlsx (Attachment B).

### **Concern 5**

*Identify any assumptions that are made, e.g., conversion factors, efficiency values, etc., which factor into the discharge calculation, but which are not part of the information that is found in the spreadsheet. Provide justification for each assumption.*

### **Response 5**

Please see attached report (Attachment A) and accompanying spreadsheet titled calculation verification STL April 28 2014 final.xlsx (Attachment B).

### **Concern 6**

*Provide the formula that the software uses to derive discharge values.*

### **Response 6**

Please see attached report (Attachment A) and accompanying spreadsheet titled calculation verification STL April 28 2014 final.xlsx (Attachment B).

**Concern 7**

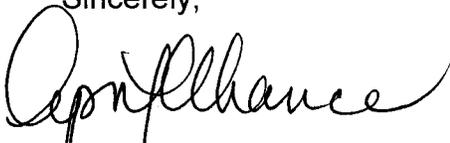
*Provide the methodology that is used to independently verify the results and accuracy of the detection and software systems.*

**Response 7**

As with other effluent monitoring systems, it is not possible to directly calibrate the monitoring system. PETNET relies on the manufacturers' recommended indirect calibration method of referencing the detector's response to a Cs-137 sealed source.

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.

Sincerely,



April Chance, CHP  
Senior Manager of Radiation Protection/Environment, Health & Safety  
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**Attachments**

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

**ATTACHMENT A**

Review of Lab Impex System Calculations Report

# PETNET Solutions

## Review of Lab Impex System Calculations

Roger Moroney, CHP

08/08/2014

### Introduction

PETNET was asked to explain the methodology used by the Lab Impex (LI) stack monitoring system to calculate activity released, and to explain certain discrepancies identified in a set of data previously submitted to the NRC.

Before PETNET began looking deeper into the methodology used by the system we believed that the data we were able to access in the LI system software, referred to as the 9205 software, was the same data used by the system to calculate the reported activity discharges. What PETNET has learned about the system architecture is that the activity calculations are performed at near real-time intervals in the CMS unit<sup>1</sup>, and then recorded at a lower resolution in the computer database. This lower resolution data is used in the 9205 software for generating the graphs, and per communications with Laboratory Impex staff, was never intended to be used to calculate the activity discharged. Nevertheless, as PETNET demonstrates below, the activity calculated from the two different starting points is very close.

### System Description

The PET Stack Monitoring System consists of the following components: a Continuous Monitoring Station - PET (CMS-PET), a PG-10 detector and flow controller mounted to a panel or on a skid (left to right in Figure 1), a sample pump, a pitot tube, DP2001 pressure transducer, and a computer with the 9205 software and communications controller (comms controller). Other optional components are available, and multiple stack systems can be connected to a single 9205 system.

The 9205 software provides a graphic overview of the system, with system and component status indicated, along with any alarm conditions. Viewing and trending of real time or historical data is available for the various parameters stored in the database. Reporting of stack releases is also provided in the 9205 software through the use of standard or custom reporting tools.

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<sup>1</sup> See diagram of system in Figure 1 (next page)

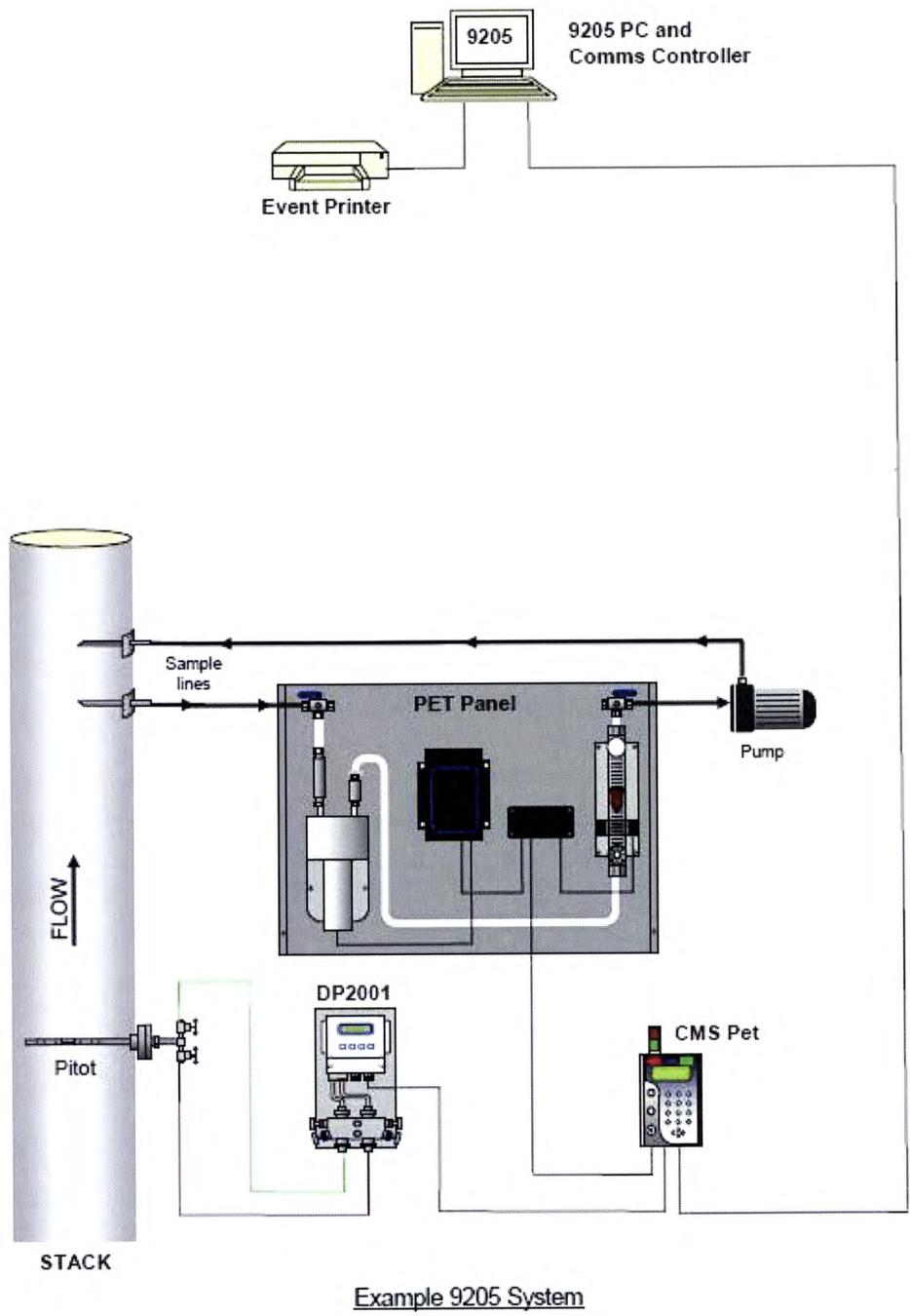


Figure 1 - PET Stack Monitoring System

*For the following sections please refer to the data contained in the spreadsheet with filename of [calculation verification STL April 28 2014 final.xlsx] transmitted electronically with this report. This spreadsheet has been reorganized to clearly separate the calculations performed from each of the two starting points as described below. The section that Mr. Lee had questions on is highlighted in gray.*

#### **Manual calculation of activity released as reported by the Lab Impex software**

Beginning with row 6 and looking at columns A to G

Column A: Date stamp

Column B: Time stamp

Column C: Time slice. Calculated by subtracting previous time stamp from current time stamp, and then converted to seconds.

Column D: “dose” in units of pCi\*sec/ml. This value is the result of taking the integrated counts over the time slice, multiplying by the manufacturer calibration factor of 0.33 (stored in the CMS), and dividing by the volume of air discharged in the time slice. This value is calculated in the CMS at near real-time intervals (~ 1 sec).

Column E: duct flow in units of cubic feet per minute as calculated by the DP2001 and CMS.

Column F: duct flow in units of milliliter per second. Calculated from Column E by converting from ft<sup>3</sup> per minute to ml/second.

Column G: activity released ( $A_i$ ) in time slice ( $Tdiff_i$ ). Calculated as follows: If the “dose” value divided by the time slice exceeds the integration threshold<sup>2</sup> (expressed as 1.014 pCi/ml as given in E3), then the activity ( $A_i$ ) in  $\mu$ Ci is calculated for the current time slice using the equation below:

$$A_i = \left[ \left( \frac{dose_i}{Tdiff_i} \right) - (Bkg Rate) \right] * duct\ flow_i * Tdiff_i * 0.000001$$

The background rate for these systems is determined by collecting a set of data from a period of time when no production or cyclotron operations is taking place, calculating the average, and then entering this value into the software. The value of 0.000001 is a conversion of pCi to  $\mu$ Ci. If the “dose” value divided by the time slice is less than or equal to the integration threshold, then a zero is recorded. This suppresses negative results.

The total activity released over any desired length of time is given by summing the individual increments.

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<sup>2</sup> See excerpt from manual in Appendix 1

## **Manual calculation of activity released using 9205 data as originally understood by PETNET and reported to NRC**

Column M: Raw count rate from detector averaged over the time slice.

Column N: "Result" recorded by 9205 software and calculated in CMS by use of 0.33 pCi/ml/cps conversion factor.

Column O: activity released ( $A_i$ ) in time slice ( $T_{diff_i}$ ). Calculated as follows: If the "result" (Column N) in pCi/ml exceeds the integration threshold (here 1.014 pCi/ml as given in E3), then the activity ( $A_i$ ) in  $\mu\text{Ci}$ , is calculated for the current time slice using the equation below:

$$A_i = [(Result) - (Bkg Rate)] * duct\ flow_i * T_{diff_i} * 0.000001$$

If the "result" value divided by the time slice is less than or equal to the integration threshold, then a zero is recorded. This suppresses negative results.

The total activity released over any desired length of time is given by summing the individual increments.

### **Comparison of activity calculated over the interval of 4/28/2014 03:47:00 to 4/28/2014 03:47:54**

In correspondence dated 06/30/2014, Dr. Lee highlighted differences in the activity increments for the time interval of 03:47:00 to 03:47:54 on 04/28/2014 data and requested an explanation for the discrepancy and identification of which one was correct. The data in these columns are calculated by the two different approaches described above. The Lab Impex system performs calculations on activity discharged at approximately one-second intervals. In order to limit the database to a manageable size, the logging of this stream occurs at a lower rate, and for the purposes of displaying data on screen, the graphs are built from lower resolution data. It was never the intent of Lab Impex that the data used to generate graphs would be used to calculate activity discharged. This was a misunderstanding of not only PETNET, but also of our primary contacts at Lab Impex. It was only after they started asking the system engineers detailed questions that the system architecture was fully understood.

The reason for the difference in the activity for a given time slice is due to the two very different quantities recorded. The actual reported discharge activity is calculated using the total counts recorded over the time interval, while the graph data are built using the average count rate over the time interval. Looking at the total activity accumulated over the interval described above (54 seconds), the integrated counts calculation totals 142.8  $\mu\text{Ci}$  while the sum using the average count rate totals 128.9  $\mu\text{Ci}$ , a difference of less than 10%. Over the longer interval of 03:17:01 to 03:52:02 (35 minutes), the sums are 878  $\mu\text{Ci}$  and 876  $\mu\text{Ci}$  respectively.

As previously discussed, PETNET has reached a greater depth of understanding of the calculations performed in the Lab Impex System software, and our conclusion remains that the system is accurately reporting the activity discharged by use of near real time data in the CMS. These are much more complex systems than normally encountered at most materials licensees where real-time recording of activity discharged is not common. We chose this type of effluent monitoring system due to the short half-life of our primary radionuclides, and the intermittent

nature of the discharges. As PETNET has illustrated, activity releases from the exhaust occur almost exclusively at a very specific point in the chemistry process where the fluoride ion is synthesized into the desired biomarker. This results in acute releases, as opposed to chronic low-level releases commonly seen in other industries.

PETNET believes that this is the best PET effluent monitor available today for this application and that provides the most accurate account of released activity.

**Appendix 1 – Excerpt from Lab Impex 9205 EMS Operating & Maintenance manual on  
Integration Threshold (page 6-2)**

background setting, these variations should cancel out giving a long-term average approximating to zero (assuming no real activity).

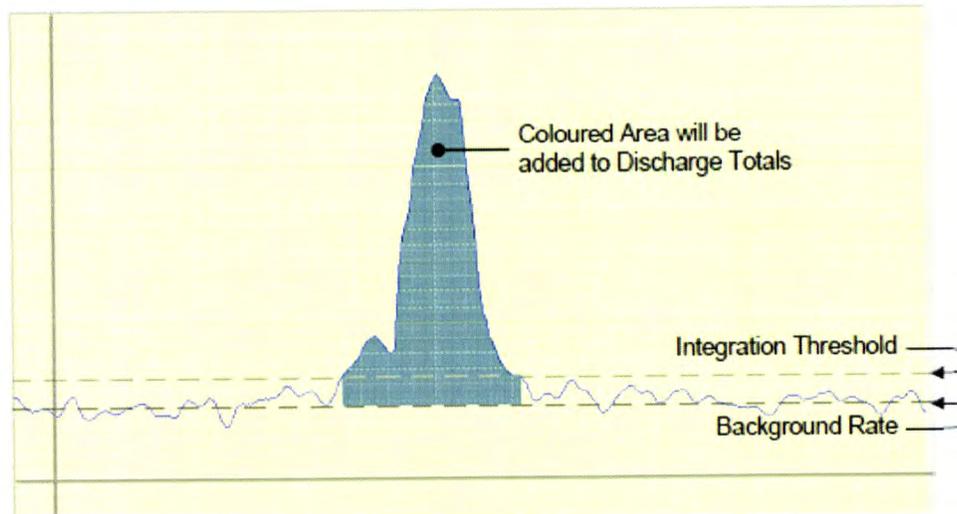
### 6.1.2. Discharge Discrimination

Stack discharge is calculated by continuously integrating the output from the monitor. For some applications, e.g. PET / Cyclotron monitoring, stack discharges occur only occasionally in short, high activity bursts. In these cases, discharge contribution from the constant detector background can be comparable to the true activity releases, resulting in artificially high discharge values. A fixed background figure can be subtracted at the monitor (see above) but if the figure used is incorrect, or if the background varies and the subtraction value is not updated, then compensation will not be accurate and the discharge result will have an error.

The 9205 Discharge Discrimination feature is designed to address this problem and when used, the CMS Background Rate parameter should be set to zero.

The Discharge discrimination parameters are 'Background Rate' and 'Percentage Threshold'. When these have been set (see below) discharge will not be accumulated until the measured result that exceeds the Integration Threshold:

$$\text{Integration Threshold} = \text{BackgroundRate} \times \left( 1 + \frac{\text{Percentage Threshold}}{100} \right)$$



Activity Graph illustrating the effect of Discharge Discrimination

**ATTACHMENT B**

“calculation verification STL April 28 2014 final.xlsx”

**(Excel file submitted electronically to Kevin Null)**

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**Kevin Null**  
US Nuclear Regulatory Comm. RIIL  
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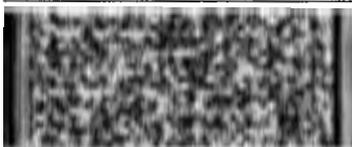
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