

# PETNET Solutions

April 10, 2014

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

**Re:** C/N 580329 and follow-up questions regarding the collection bag system for F-18 labeled FDG and F-18 labeled AV-45 effluent release at the PETNET St. Louis facility.

Dear Mr. Null:

Please accept this letter as PETNET's response to the Nuclear Regulatory Commission's (NRC) Conversation Record (580329) regarding follow-up questions about the bag collection system located at the PETNET St. Louis facility.

## **Concern 1:**

- A. *Please describe how you will control the flow and time of purging so that the volume of the purging gas will not exceed 100 liters.*
- B. *Submit procedures that will be followed for: (1) the nitrogen purging process and verification that the all connections for the collection system are intact; (2) detection and correction of malfunctions with the gas collection system; (3) the release of F-18 labeled FDG and the F-18 labeled AV-45 compound gases from collection bags.*

## **Response 1**

- A. The chemistry module is a programmable unit that is designed for the production of radiopharmaceuticals. The chemistry module performs its own internal calibration prior to each run to ensure that the unit is properly sealed and correctly configured. During the first 20 minutes of synthesis the product undergoes a drying process, which accounts for the emission of radioactive gas. The programmable module pumps out a volume of approximately 20-22 L for one cleaning cycle and one FDG synthesis run. The AV-45 compound is manufactured on a module that is designed for two syntheses with a total expected nitrogen purge volume of 40-44 L. Thus, the programmable module controls the volume of emitted gas ensuring the gas never exceeds 100 L.
- B. The PETNET operating procedure, "Exhaust Containment for the Chemistry Modules – St Louis" (SOP #D0012328), is attached for your review as Attachment A.

#### **Concern 4**

*Provide the minimum detectable concentration based on the conversion factor of 0.40 pCi/ml per cps that was described in Attachment B to your March 4 letter.*

#### **Response 4**

The MDC equation is:

$$MDC = \frac{2.71 + 4.65(\sqrt{B \times T})}{T \times E}$$

Where:

B = background count rate = 2.4 counts per second (cps)

T = time constant = 60 seconds

E = efficiency parameter = 0.4 pCi per mL per cps

Inserting these values into the equation the resultant MDC is 0.39 pCi/mL.

#### **Concern 5**

*Your response did not describe how you will identify if there is a leak into worker spaces. Please address this.*

*In addition to the above, please address the following:*

*In order to be assured that the engineering controls are functional and effective, please commit to collecting effluent release data for 30 days beginning from the date the controls are approved in a license amendment. After the 30 day period, you may submit a request for a license amendment that includes the 30 days of effluent release data, and request authorization for relief of the garden access controls.*

#### **Response 5**

Site personnel currently have the ability to identify a leak into their work space by an alarming area monitor (set at 5 mR/hr) that is installed adjacent to the hot cell and by the highly sensitive foot & hand GM detectors located within the production and pharmacy rooms.

There is not an alarming concern for effluent to leak into the general room air due to the negative pressure inside the hot cell where the containment bag is located. This is the same system that is relied upon for normal manufacturing.

PETNET commits to collecting effluent release data for 30 days beginning from the date the controls are approved in a license amendment. After the 30 day period, PETNET will submit a request for a license amendment that includes the 30 days of effluent release data, and request authorization for relief of the garden access controls.

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  
Senior Manager of Radiation Protection/Environment, Health & Safety  
Molecular Technologies Division of  
Siemens Molecular Imaging  
(PETNET, Cyclotrons and Sources)  
810 Innovation Drive  
Knoxville, TN 37932  
(865) 308-3887 mobile  
(865) 218-6355 office  
[april.chance@siemens.com](mailto:april.chance@siemens.com)

**Attachments**

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

ATTACHMENT A

Exhaust Containment for the Chemistry Modules – St Louis  
SOP #D0012328

STANDARD OPERATING PROCEDURE		
Exhaust Containment for the Chemistry Modules – St Louis	SOP #: D0012328	
Originator: Eric Webster	Revision:	A
Process Owner: Eric Webster		
Mgmt. Approval: Tigran Sinanian		
Q&R Approval: April Chance	Page 1 of 2	
CONFIDENTIAL. NOT FOR REPRODUCTION OR DISTRIBUTION.		

**I. PURPOSE**

The purpose of this procedure is to provide a method for collecting the exhaust from the chemistry modules (i.e., Explora and GN) at the St Louis manufacturing facility.

**II. RESPONSIBLE**

The Radiation Safety Officer and manager of the St Louis facility are responsible for carrying out this procedure.

**III. SCHEDULE**

This procedure should be executed during all radioactive synthesis at the PETNET St Louis facility.

**IV. EQUIPMENT AND MATERIALS**

ITEM	QUANTITY	PART NUMBER
Tedlar Bag, with Swagelok adapter, 100 L	As Needed	PN0002998 or equivalent
Tedlar Bag, with Swagelok adapter, 80 L	As Needed	PN0003000 or equivalent
Teflon tubing	As Needed	

**V. PROCEDURE**

**A. Description of containment system**

1. The containment system used will be a Tedlar bag that is contained in the shielded hot cell.
2. The 100 L bags have enough volume to allow for a combination of four (4) synthesis and four (4) "Cleaning" recipes (80-88 L) on the Explora chemistry module. The 80 L bags have enough volume to allow for a combination of two (2) synthesis and two (2) "Cleaning" recipes on the GN module. A smaller bag may be used if fewer syntheses are going to be performed.

**B. Evacuation of the containment system**

1. Perform and document radiation exposure (mR/hr) surveys prior to opening the door to the hot cell.
2. Perform and document radiation exposure (mR/hr) surveys of the bags containing exhaust from the previous business day.
3. Once exposure levels (at 30 cm from each bag) are verified and documented below 5 mR/hr (taking into account the elevated background levels from adjacent bags), remove the inlet tubing from bag and empty the bag's content (with the use of a vacuum pump) within the hot cell to be evacuated by the filtered ventilation system.

**C. Pre operation checks**

1. Verify that the Tedlar Bag is not connected to the chemistry module.
2. Perform all module cleaning procedures according to the appropriate cleaning procedures or Master Formula.
3. Connect the Tedlar Bag to the chemistry module.
4. Perform a Self-Test recipe on the chemistry module.
5. Complete the "Exhaust Containment" form to verify that the Tedlar Bag is connected to the chemistry module.
6. During each synthesis, review stack's monitor data (e.g., Daily, Monthly Releases) to evaluate if there is a release and document the total monthly released activity.

STANDARD OPERATING PROCEDURE	
Exhaust Containment for the Chemistry Modules – St Louis	SOP #: D0012328
Originator: Eric Webster Process Owner: Eric Webster Mgmt. Approval: Tigran Sinanian Q&R Approval: April Chance	Revision: A
Page 2 of 2	
CONFIDENTIAL. NOT FOR REPRODUCTION OR DISTRIBUTION.	

7. Inform the site RSO and immediately contact the RP/EHS Department for instructions anytime there is a release greater than the Action Limits shown below:

Daily	769 $\mu$ Ci
Weekly	3846 $\mu$ Ci
Monthly	16667 $\mu$ Ci
Yearly	200,000 $\mu$ Ci

8. Visually inspect the collection system hardware for obvious issues, evaluate root cause analysis and resolve as needed. Prior to the next synthesis run on the affected chemistry module, ensure Steps C.1 through C.6 of this procedure are completed.
9. Record, as a minimum, the Monthly released activity on the "Exhaust Containment" form.

**D. Maintenance**

1. Daily, when used, empty the Tedlar bag from the previous day.
2. Replace the bag at least quarterly.

STANDARD OPERATING PROCEDURE		
Exhaust Containment for the Chemistry Modules – St Louis		SOP #: D0012328
		Revision A
		Page 1 of 1
CONFIDENTIAL. NOT FOR REPRODUCTION OR DISTRIBUTION.		

A. Verification Log for Tedlar Bag

Module Number:

Month:

Date FY2014	B. Containment Evacuation		C. Pre-Operation Checks		Monthly Activity ( $\mu$ Ci) or Activity that exceeds an Action Limit	
	Exposure Survey (mR/hr)	Emptied Bag at beginning of business day	Verified no leaks by monitoring stack monitor			Completed by (Initials)
			Hot Cell	Bag(s)		
1			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
2			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
3			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
4			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
5			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
6			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
7			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
8			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
9			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
10			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
11			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
12			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
13			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
14			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
15			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
16			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
17			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
18			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
19			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
20			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
21			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
22			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
23			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
24			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
25			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
26			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
27			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
28			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
29			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
30			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		
31			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No		

STANDARD OPERATING PROCEDURE	
Exhaust Containment for the Explora chemistry modules – St Louis	SOP #: D0012328
	Revision A
	Page 1 of 1
CONFIDENTIAL. NOT FOR REPRODUCTION OR DISTRIBUTION.	

**A. Maintenance Log for Tedlar Bag**

Explora Module Number: \_\_\_\_\_ Year: \_\_\_\_\_

	Quarter 1 (Jan – Mar)	Quarter 2 (Apr – June)	Quarter 3 (July – Sept)	Quarter 4 (Oct – Dec)
Initials and Date of person changing bag				

Explora Module Number: \_\_\_\_\_ Year: \_\_\_\_\_

	Quarter 1 (Jan – Mar)	Quarter 2 (Apr – June)	Quarter 3 (July – Sept)	Quarter 4 (Oct – Dec)
Initials and Date of person changing bag				

GN Module Number: \_\_\_\_\_ Year: \_\_\_\_\_

	Quarter 1 (Jan – Mar)	Quarter 2 (Apr – June)	Quarter 3 (July – Sept)	Quarter 4 (Oct – Dec)
Initials and Date of person changing bag				

GN Module Number: \_\_\_\_\_ Year: \_\_\_\_\_

	Quarter 1 (Jan – Mar)	Quarter 2 (Apr – June)	Quarter 3 (July – Sept)	Quarter 4 (Oct – Dec)
Initials and Date of person changing bag				

## Taylor, Tiresha

---

**From:** Null, Kevin  
**Sent:** Tuesday, May 06, 2014 12:39 PM  
**To:** Taylor, Tiresha  
**Subject:** FW: Siemens response to Conversation Record 580329  
**Attachments:** 2014-04-10 Siemens 2nd Response Letter to NRC Memo 580329\_STL Gas Collection.pdf

---

**From:** Davila Jr, Ramon [<mailto:ramondavila@siemens.com>]  
**Sent:** Tuesday, May 06, 2014 9:45 AM  
**To:** Null, Kevin  
**Subject:** RE: Siemens response to Conversation Record 580329

Kevin,

Yes, you are correct. I named the file correctly, but dated it incorrectly on the letter. It is attached with correct date.

Just a reminder to note is that the procedure and associated forms are currently being revised in accordance with our conversations last week.

Ramon

---

**From:** Null, Kevin [<mailto:Kevin.Null@nrc.gov>]  
**Sent:** Tuesday, May 06, 2014 7:11 AM  
**To:** Davila Jr, Ramon  
**Subject:** RE: Siemens response to Conversation Record 580329

Hi Ramon,

Should your attached letter have been dated April 10/? The conversation that we had regarding the additional questions was on March 14.

Kevin

---

**From:** Davila Jr, Ramon [<mailto:ramondavila@siemens.com>]  
**Sent:** Thursday, April 10, 2014 7:46 AM  
**To:** Null, Kevin  
**Cc:** Lee, Peter; Chance, April  
**Subject:** Siemens response to Conversation Record 580329

Kevin,

The response letter is attached for your review.

Hopefully you have sufficient information to provide your staff with a better understanding our gas collection procedure and ALARA Program. Please do not hesitate to contact me if you have additional questions.

We will see you in St. Louis on April 29, 2014 for the 6:30 am production run and on April 30, 2014 at 1 am for the bag venting process, unless you request a different time.

Thanks,

Ramón Davila, Jr, MBA, RRPT  
Regional Health Physicist  
Siemens MI / PETNET Solutions  
865-332-6594 (cell)  
865-218-3295 (office)  
865-218-3018 (fax)  
[ramondavila@siemens.com](mailto:ramondavila@siemens.com)

---

**From:** Null, Kevin [<mailto:Kevin.Null@nrc.gov>]  
**Sent:** Wednesday, April 09, 2014 4:18 PM  
**To:** Davila Jr, Ramon  
**Cc:** Lee, Peter  
**Subject:** response

Hi Ramon,

Please make sure you send me a hard copy of your response. But also, please send me an e-mail of the response and provide a courtesy copy to Peter.

Thanks,

Kevin

This message and any attachments are solely for the use of intended recipients. The information contained herein may include trade secrets, protected health or personal information, privileged or otherwise confidential information. Unauthorized review, forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you are not an intended recipient, you are hereby notified that you received this email in error, and that any review, dissemination, distribution or copying of this email and any attachment is strictly prohibited. If you have received this email in error, please contact the sender and delete the message and any attachment from your system. Thank you for your cooperation

This message and any attachments are solely for the use of intended recipients. The information contained herein may include trade secrets, protected health or personal information, privileged or otherwise confidential information. Unauthorized review, forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you are not an intended recipient, you are hereby notified that you received this email in error, and that any review, dissemination, distribution or copying of this email and any attachment is strictly prohibited. If you have received this email in error, please contact the sender and delete the message and any attachment from your system. Thank you for your cooperation