

PETNET Solutions

June 3, 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 site visit to observe the operation and implementation of the gas collection system designed to trap and hold fluorine-18 labeled FDG and fluorine-18 labeled AV-45 gaseous effluent prior to being released 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 implementing the bag collection system located at the PETNET St. Louis facility.

Concern 1:

A comprehensive standard operating procedure (SOP) that will include, but not be limited to:

- a. *A commitment that the facility will control fluorine-18 gaseous effluent releases to no greater than 214 millicuries per year in order to demonstrate compliance with the limit specified in 10 CFR 20.1101 (d).*
- b. *A commitment to perform a daily evaluation of the integrity of gas collection bags, associated tubing, and fittings, and include a description of the criteria that will be used to determine when bags, associated tubing, and fittings will be replaced.*
- c. *A description of the minimum frequency that bags, associated tubing, and fittings will be replaced.*
- d. *A description of the minimum amount of time that the gas will be held for decay in a collection bag prior to being released.*
- e. *A clarification of the method that will be used to evacuate the bag, i.e., manually or by a vacuum pump.*
- f. *A commitment that the facility will maintain an operable backup vacuum pump for evacuating collection bags in the event of a failure of the primary pump.*
- g. *A set frequency and protocol for checking the lab impex monitoring system detector's response to radiation using a check source.*
- h. *The protocol that will be followed if the exhaust fan fails.*

- i. *A description of a corrective action program that will be implemented if there is an unexpected fluorine-18 gaseous effluent leak that is identified by the lab impex system.*
- j. *A description of the threshold of fluorine-18 that, if released as a gas effluent, would result in an investigation and evaluation to determine root and contributing causes and development of corrective actions to prevent recurrence.*
- k. *A description of ALARA considerations and limitations that will be placed on the amount of fluorine-18 that can be released, and actions that will be taken if those levels are exceeded.*

Response 1

The site specific SOP for PETNET St. Louis's Gas Collection system is attached for your review. Please note that this procedure is going through corporate's approval process.

Concern 2

A commitment to amend the NRC license before modifications are made to the gas collection system, or the effluent monitoring and filtration systems.

Response 2

PETNET commits to amending its NRC issued license prior to implementing any modifications to the Gas Collection System and/or effluent systems.

Concern 3

A commitment that the lab impex effluent monitoring system will be calibrated using a positron emitting gas at a specific frequency, or that the device will be returned to the manufacturer for calibration at a specific frequency.

Response 3

PETNET has communicated with the detector manufacturer, Lab Impex. Per their recommendation the site will perform a Positron Gas Calibration (using C-11) if/when the Quarterly Cs-137 Calibration Check exceeds 10% of installed value of 0.40 pCi/ml per cps.

Concern 4

A commitment that on a quarterly basis, PETNET staff will perform independent calculations to verify the lab impex system's assessment of activity that is being released.

Response 4

PETNET commits to performing independent verification calculations of the released activity. We are currently working with the Lab Impex Engineering Department to better understand how the system derives the calculations and on how we can attain the necessary raw data, which are hidden and only available to Lab Impex, for our verification calculations.

Concern 5

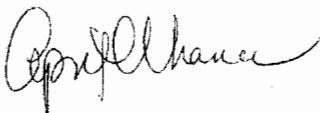
Provide the raw data generated by the lab impex system from 3 previous effluent releases. Also, provide an assessment of the activity released based on hand calculations, along with a comparison to the activity released according to the lab impex system for each corresponding time.

Response 5

PETNET has provided the Lab Impex data to the NRC for the past four weeks. As stated in Response 4, we do not have access to the pertinent raw data required to perform verification calculations. PETNET is collaborating with Lab Impex to resolve this issue.

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
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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 Explora chemistry modules – St Louis	SOP #: D0012328	
Originator: Eric Webster Process Owner: Ramon Davila Mgmt. Approval: Tigran Sinanian Q&R Approval: April Chance	Revision:	A
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I. PURPOSE

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

II. RESPONSIBLE

The Radiation Safety Officer and/or manager of the St Louis facility are responsible for ensuring that this procedure is properly performed by trained personnel.

III. SCHEDULE

This procedure shall 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 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.
3. A vacuum pump to evacuate the Collection Bag. A back-up pump will be available at all times.

B. Evacuation of the containment system

1. Prior to the following steps, ensure that the collected gas has decayed a minimum of 8 half-lives.
2. Perform contact radiation exposure rate (mR/hr) surveys prior to opening the door to the shielded cell.
3. Perform radiation exposure rate (mR/hr) surveys of the bags at 30 cm containing exhaust from the previous business day and document on "Exhaust Containment form" associated with this document.
4. Once exposure levels are verified and documented below 5 mR/hr (taking into account the elevated background levels from adjacent bags), perform the following:
 - a. Remove the inlet tubing from collection bag.
 - b. Correctly attach tubing to the vacuum pump inlet.
 - c. Turn on pump and verify the bag's content is emptied (not inflated) within the shielded cell for evacuation through the filtered ventilation system.

C. Operational checks of Chemistry Module Prior to Beginning of Synthesis (BOS):

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.

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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 associated with this document, to verify that the Tedlar Bag is connected to the chemistry module.
6. Perform second person verification that the bag is emptied and properly connected for all production runs.
7. During the production day, periodically review the stack monitor data to evaluate if there is a release. At the end of the production day, document the accumulated daily released activity.
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.7 of this procedure are completed.

D. Notifications

1. Follow the table below for instructions on the immediate action(s) to be taken in the event of exceeding an effluent release limit. If the Lab Impex indicates a yearly release of 171,200 μCi (80% of Yearly Limit), immediately contact the Corporate RSO by phone. The Radiation Safety Committee will evaluate actions to be taken.

	Activity (μCi)	Action
Daily	892	Notify site RSO
Monthly	17,833	Notify site RSO & RP/EHS
Quarterly	42,800	Notify site RSO & RP/EHS
Yearly	171,200	Notify site RSO, RP/EHS, & CRSO
NRC Constraint	214,000	Immediately Stop Production

E. Unusual Events

1. Non-Operational Detector System
 - a. Immediately contact site RSO and RPH
 - b. Attain Quarterly released activity
 - i. If level is below the Quarterly Limit, proceed with production
 - ii. If level exceeds any limit greater than the Quarterly Limit, immediately halt further production
2. Non-Operational Exhaust Ventilation System
 - a. Immediately determine if effluent is being released into the pharmacy work areas
 - i. Alarming foot & hand monitors
 - ii. Readings on installed area monitors
 - b. If either detection system mentioned above is indicating a release
 - i. Immediately evacuate the area
 - ii. Close all doors to the pharmacy
 - iii. Restrict access to the pharmacy
 - iv. Contact site RSO and RP/EHS for further instructions

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3. Unexpected effluent leak

- a. Identify the source of the leak
- b. Notify the site RSO and RPH
- c. If necessary, stop and/or isolate the source of the leak
- d. Minimize the spread of the leak
- e. Identify if effluent has not leaked into room
- f. Evacuate the pharmacy and secure access to facility until radiation levels are at background
- g. Perform Root Cause Analysis for any release of F-18 that is greater than 10 pCi/ml.

F. Maintenance

Regulatory Compliance Task Frequency			
SOP #	Task	Due Date	By
Daily			
D0012328	Empty decayed gas in Tedlar bag from the previous day		
D0012328	Inspect and verify integrity of the Tedlar Bag		
D0012328	Inspect and verify integrity of the collection tubing		
RC-15	Verify Stack Discharge Values are below the site specific limits		
Weekly			
RC-16	Exhaust System Check		
RC-17	CPCU Filter Replacement		
Monthly			
RC-5	Dosimeter Exchange		
RC-6	Dose Reports - Review		
RC-8	Area Dosimeter Exchange		
RC-17	Replace prefilters		
Quarterly			
D0012328	Replace Tedlar Bag		
RC-14	Area Monitor Alarm Checks		
RC-15	LIS Stack Monitor Calibration Check (Conversion Factor Calculation)		
RC-15	LIS Verification Check on Computer's Calculations		
Semi-Annually			
RC-17	Ventilation System Maintenance		
Annually			
D0012328	Inspect & Replace collection tubing		
RC-16	Velometer Calibration		
Miscellaneous			
RC-15	Positron Gas Calibration (using C-11) if/when Quarterly Calibration Check exceeds 10% of installed value of 0.40 pCi/ml per cps		
RC-17	Replace HEPAs when pressure drop reaches twice the installed value		
RC-17	Replace carbon filters when avg weekly release doubles, over a four-week period		
Grace Period			
Daily	0 Days	Quarterly	3 Days
Weekly	1 Day	Semi-Annually	3 Days
Monthly	2 Days	Annually	5 Days

Null, Kevin

From: Davila Jr, Ramon <ramondavila@siemens.com>
Sent: Tuesday, June 03, 2014 4:00 PM
To: Lee, Peter; Null, Kevin
Subject: Siemens PETNET response to CR 580329 dated 4-29-14
Attachments: 2014-06-03 Siemens response to NRC Gas Collection Questions Memo dated 04-29-2014.pdf

Kevin,

The response is attached for your review.

Take care!

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