PETNET Solutions

March 29, 2013

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

Re: PETNET St. Louis Effluent Control and Monitoring Issue for Radioactive Materials License No. 41-32720-03

Dear Mr. Null:

Please accept this letter and associated documents as PETNET's submission for resolving the Nuclear Regulatory Agency's (NRC) concerns with the currently installed filtered exhaust system located at the PETNET St. Louis facility.

Executive Summary

PETNET Solutions is committed to ethical and responsible actions. As such, the Siemens RP/EHS Department has conducted extensive measurements of effluent releases at the St. Louis facility in order to determine the exposure to individuals occupying the areas within the garden, patio, and public sidewalks. Several engineering controls have been considered and administrative controls were implemented restricting access to the areas of concern. While results of a few grab samples resulted in short-term air concentrations exceeding the 10 CFR 20 Appendix B,Table 2 value, the annual average air concentration does not exceed that level.

The collected data provides clear evidence that the effluent releases have been compliant with 10 CFR 20 Appendix B, Table 2 Effluent Limit (F-18 < 1E-7 µCi/mL), along with NRC's constraint level (20% of Table 2 Limit).

Assessment Objectives

As noted in the historical timeline (Attachment A), concern about radioactive effluents were expressed when PETNET's new RAM Application submitted as a result of the transfer of regulatory authority from the State of Missouri to NRC. The design of the ventilation exhaust system was acceptable at the time the site was constructed; however, the NRC was not satisfied with the design and requested PETNET evaluate the levels of radiation existing in the restricted and unrestricted areas of the Tenet St. Louis University Hospital (SLUH).

PETNET provided the NRC with calculated effluent concentrations using the EPA-approved COMPLY program. The results indicated that the facility was in compliance. However, because of the location of the effluent exit point and the proximity of the 18

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story hospital tower, these results were deemed unacceptable by the NRC. Consequently, several meetings were conducted among NRC, PETNET, St. Louis University (SLU) and SLUH with the goal of determining a solution that would include administrative and engineering controls. It should be noted that at this time no direct field measurements of the environmental air had been conducted. During this same time period, the SLUH administrators had requested access to the patio balcony, even though this area was never designed to allow access to the public. To meet the objectives of both the NRC and the SLUH administrators, PETNET made the decision to conduct actual field measurements of the environmental air. That effort produced 84 effluent samples within the patio balcony, garden, egress sidewalk, and public sidewalks.

The results of all calculated effluent air concentrations and associated dose equivalent exposures, along with the sampling locations and the worksheets used to derive the results, are provided in Attachment B. The data from actual air samples were taken onsite in May, September, December 2012, and March 2013.

Conclusions

The collected air sample data provides clear evidence that effluent releases are, and have been, compliant with 10 CFR 20.1302(b)(1)(i). The data also shows that the annual average concentration is below the constraint level (20% of Table 2 Level) in 10 CFR 20.1101(d).

The PETNET RP/EHS Department has been thoroughly involved with understanding the issues with effluents resulting from manufacture of PET radiopharmaceuticals for over a decade. Siemens has taken a systematic approach to ensuring PET effluent releases do not expose workers or the general public to levels above the regulatory limits of 10 CFR 20. The environmental sampling proves that the current system is in compliance.

Several engineering controls have been discussed during the last year, including collection, compression and decay of volatile releases, additional filtration, and air cannons. Based on the evidence provided by the direct field measurements, PETNET is in compliance with all regulatory requirements and believes that no further actions are required. In the course of discussions with the NRC, various exposure scenarios have been proposed, such as during an emergency egress situation or a potential re-concentration of effluents due to building wake effects. PETNET does not find these to be credible scenarios in that the exposure time is so minimal, or the possibility of occurrence so remote, as to have no significant impact on the annual dose due to effluents.

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
Molecular Technologies Division of
Siemens Molecular Imaging
(PETNET, MIBR, Cyclotrons and Sources)
810 Innovation Drive
Knoxville, TN 37932
(865) 308-3887 mobile
(865) 218-6355 office
april.chance@siemens.com

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

ATTACHMENT A
HISTORICAL TIMELINE

CONVERSATION RECORD (time) (date) | TIME | DATE 11/2/11

VISIT F CONFERENCE TELEPHONE X

F INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Roger Moroney	PETNET	865-218-2595

SUBJECT

C/N 318795

SUMMARY

After review of PETNET's application for a new cyclotron production license at their St. Louis location, I requested that the applicant submit the following additional information:

1. Submit an organizational chart that describes PETNET's management structure, reporting paths, and the flow of authority between executive management and the Radiation Safety Officer (RSO). Also, relative to radiation safety responsibilities and management control of licensed operations, please describe the joint venture between Saint Louis University and PETNET Solutions. Include the delineation of responsibility between both organizations.

2. Page number 55876 of the Federal Register, Volume 72, Number 189, regarding the expanded definition of byproduct material states that individuals identified by the applicant with appropriate training such as engineers, physicists, radiochemists, etc., will be recognized as authorized users under a Part 30 license for the production of accelerator-produced radionuclides on a new NRC license if the applicant can demonstrate and confirm that these individuals performed essentially the same radionuclide production activities using an accelerator under the NRC's waiver, and as long as their duties and responsibilities did not significantly change. Therefore, please identify those individuals who meet these criteria that you wish to be named as authorized users on the license.

3. Submit the make and model number of the sealed sources that are listed on page 5 of your application.

4. Pages 120 and 121 of the application: Both facility diagrams are marked to be withheld because they contain security-related information. However, after review of the diagrams they do not appear to describe the exact location of material, and therefore would not need to be protected. Please resubmit these diagrams without a referencing them as security-related information. If necessary, also remove any references from the diagrams to specific locations where material is used or stored..

5. Please conduct and submit results of surveys in all areas (both inside and outside of the building) directly adjacent to the cyclotron (both restricted and unrestricted areas) while the cyclotron is in operation so that we can evaluate the levels of radiation that exist. Please include the area directly above the cyclotron that is an outdoor area.

6. Page 21 of the application (4th bullet): Given that significant exposure can occur when handling targets, windows, and target holders, please define criteria for determining when and if remote handling tools will be utilized when handling targets.

7. Page 21 of the application (5th bullet): Define the alarming dosimeter set point to assure that the set point is set at a fraction of regulatory limits.

8. Page 22 of the application (2nd, 3rd and 4th bullets): Define the frequency at which safety and warning devices and interlocks will be checked for function. Describe how each feature will be checked to verify functionality.

9. Regarding the section on page 22 entitled, "Effluent Control & Monitoring": Provide a description and diagram of the point of release of effluent from the cyclotron/pharmacy operations. Please also describe the point of release relative to the nearest air intake of the SLU hospital, entrance and exits to the hospital, and the nearest unrestricted areas.

10. Submit results of effluent released for CY 2010 and 2011 (to date), and PETNET's assessment of public dose from this data.

11. Explain or provide justification as to why effluent from the cyclotron is not filtered.

12. Describe the average concentration of F-18 released per day and estimated total activity released per year and submit an assessment that demonstrates that these values are in compliance with NRC regulations.

13. Describe your program for verifying the integrity of the delivery lines that supply F-18 to the hot cells and mini-cells from the cyclotron. Describe safety procedures for changing out delivery lines that may be contaminated with F-18.

14. Define more clearly the specific frequency for conducting both exposure rate surveys and contamination surveys.

15. Submit a "Delegation of Authority" for the Corporate RSO. Also submit a delegation of authority for the facility RSO.

ACTION REQUIRED

Submit a written response and refer as additional information to Control Number 318795

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Kevin Null		11/2/11

ACTION TAKEN

SIGNATURE	TITLE	DATE

PETNET Solutions

December 28, 2011

Kevin G. Null
Materials Licensing Branch
U.S. NRC Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

Re: **Control Number 318795 - Response to questions on NRC Radioactive Material License (production of NARM) Application for our existing PETNET facility in St. Louis, MO License # 40-32720-03; docket # 030-38230**

Dear Mr. Null,

The purpose of this letter is to respond to questions from a telephone conversation on November 2, 2011 regarding the NRC Radioactive Material (RAM) License (production of NARM) for the existing PETNET Solutions, Inc. facility in St. Louis MO. The response is contained below and will include the original question.

We believe that we have provided all the information that the Agency needs to grant this request. If you have any questions, please contact me at the number below, or contact Roger Moroney at (865) 218-2595.

Sincerely,

April Chance, CHP
Manager of Radiation Protection/EHS
Molecular Technologies Division of
PETNET Solutions, Inc.
(865) 308-3887 mobile
(865) 218-6355 office
april.chance@siemens.com

att: Response to Questions

cc: Rita Gentilcore, M.S., R.Ph., Facility RSO
Roger Moroney, CHP, Regional Health Physicist

Response to Questions

1. *Submit an organizational chart that describes PETNET's management structure, reporting paths, and the flow of authority between executive management and the Radiation Safety Officer (RSO). Also, relative to radiation safety responsibilities and management control of licensed operations, please describe the joint venture between Saint Louis University and PETNET Solutions. Include the delineation of responsibility between both organizations.*

   Please see the organizational chart in Attachment A. The PETNET facility at St. Louis University is not a joint venture. PETNET Solutions is contracted to operate the cyclotron and radiopharmacy on behalf of St. Louis University. The contract between St. Louis University Hospital and PETNET includes a requirement that PETNET is solely responsible for administrative, operational, sales, and regulatory support necessary to operate the facility. Therefore PETNET holds all required licenses. Since the PETNET RSO is a member of the St. Louis University Radiation Safety Committee the host does have visibility to any issues that may arise and the St. Louis University RSO is familiar with PETNET's operations.

2. *Page number 55876 of the Federal Register, Volume 72, Number 189, regarding the expanded definition of byproduct material states that individuals identified by the applicant with appropriate training such as engineers, physicists, radiochemists, etc., will be recognized as authorized users under a Part 30 license for the production of accelerator-produced radionuclides on a new NRC license if the applicant can demonstrate and confirm that these individuals performed essentially the same radionuclide production activities using an accelerator under the NRC's waiver, and as long as their duties and responsibilities did not significantly change. Therefore, please identify those individuals who meet these criteria that you wish to be named as authorized users on the license.*

   The following individuals were requested to be named as Authorized users (AU) in the original application, which included supporting documentation.

   1. Rita Gentilcore, M.S., R.Ph. (Authorized Nuclear Pharmacist)
   2. John Beyer, R.Ph. (Authorized Nuclear Pharmacist)
   3. Ranajit Bera, Ph.D. (Chemist)
   4. David Williams (Field Service Engineer-Cyclotron)
   5. Sailom Boualaphanh (Field Service Engineer-Cyclotron)
   6. Brad Knorr (Field Service Engineer- Cyclotron)
   7. Lucas Fernandez (Area Service Manager-Cyclotron)

Since the submission of the application two individuals, Mr. David Williams and Mr. Brad Knorr, have left the company. The revised AU list is now:

1. Rita Gentilcore, M.S., R.Ph. (Authorized Nuclear Pharmacist)
2. John Beyer, R.Ph. (Authorized Nuclear Pharmacist)
3. Ranajit Bera, Ph.D. (Chemist)
4. Sailom Boualaphanh (Field Service Engineer-Cyclotron)
5. Lucas Fernandez (Area Service Manager-Cyclotron)

All of these individuals have performed the same duties for production of radionuclides under the NRC waiver as are being requested on the license application. Training certificates and experience information were included in the original application. Mr. Boualaphanh and Mr. Fernandez are named as AUs on Agreement State licenses, which were also included in the original application.

3. *Submit the make and model number of the sealed sources that are listed on page 5 of your application.*

Please remove the ^{57}Co source from the list. This source belongs to the Hospital and was returned to them. As all PETNET uses are PET radionuclides that emit 511 keV photons, a lower energy dose calibrator source is not needed.

The ^{22}Na is manufactured by Eckert & Ziegler and the model number is RV-022-200U. We do not currently possess a ^{137}Cs dose calibrator source however most likely we will acquire an Eckert & Ziegler RV-137-200 source when the current ^{22}Na has decayed below a usable level.

4. *Pages 120 and 121 of the application: Both facility diagrams are marked to be withheld because they contain security-related information. However, after review of the diagrams they do not appear to describe the exact location of material, and therefore would not need to be protected. Please resubmit these diagrams without a referencing them as security-related information. If necessary, also remove any references from the diagrams to specific locations where material is used or stored.*

Per the telephone discussion between Roger Moroney and Kevin Null the diagrams will remain as is.

5. *Please conduct and submit results of surveys in all areas (both inside and outside of the building) directly adjacent to the cyclotron (both restricted and unrestricted areas) while the cyclotron is in operation so that we can evaluate the levels of radiation that exist. Please include the area directly above the cyclotron that is an outdoor area.*

   Please see the survey results in Attachment B.

6. *Page 21 of the application (4^{th} bullet): Given that significant exposure can occur when handling targets, windows, and target holders, please define criteria for determining when and if remote handling tools will be utilized when handling targets.*

   Please see the excerpt from our procedure addressing radiation protection during cyclotron maintenance:

   A. Survey work area in the cyclotron to determine the exposure rate.

   B. Calculate the estimated exposure for the job by estimating the time it will take to perform the job.

   C. If the estimated exposure is greater than 100 mR whole body and/or will cause the employee to exceed his/her ALARA level II for the quarter, allow more decay before performing the job.

   D. When applicable use remote handling devices (tongs) when handling contaminated and/or activated parts.

   Before handling targets rinse and dry them to minimize exposure and contamination.

   PETNET requires staff to assess the radiological conditions prior to performing maintenance inside of the cyclotron shields. The main task that requires the use of tongs is handling the target window, as it is not practical or necessary for most other components. The target body assembly is handled by the end opposite of the entrance window and is typically less than 200 mR/h. The last statement in the excerpt, above, also greatly reduces any residual radiation field from the desired PET radionuclide. PETNET maintains sufficient spare target bodies to allow a freshly removed target body to decay prior to rebuilding.

7. *Page 21 of the application (5th bullet): Define the alarming dosimeter set point to assure that the set point is set at a fraction of regulatory limits.*

   The current PETNET procedure requires that the dose alarm is set at 80 mR, the dose rate alarm is set at 1000 mR/h, and the chirp rate is one per mR. While the dose rate alarm set point might seem high, it is based on experience and a desire to eliminate nuisance alarms.

8. *Page 22 of the application (2nd, 3rd and 4th bullets): Define the frequency at which safety and warning devices and interlocks will be checked for function. Describe how each feature will be checked to verify functionality.*

   Current PETNET procedures require a quarterly check of the shield interlocks, emergency shut-down switch, and the area monitor alarm set points. The steps necessary to functionally check or test each system are given in the procedure and these tests are recorded by the site and reviewed by the RSO and, during the annual audit, by corporate personnel.

9. *Regarding the section on page 22 entitled, "Effluent Control & Monitoring": Provide a description and diagram of the point of release of effluent from the cyclotron/pharmacy operations. Please also describe the point of release relative to the nearest air intake of the SLU hospital, entrance and exits to the hospital, and the nearest unrestricted areas.*

   Please see the diagram in Attachment C. The exhaust point is in a garden area elevated approximately eight feet above street level. There are no intakes on the front side of the hospital. There are doors on the front side of the hospital that open onto an upper patio, with stairs that descend from each side down to the garden area. Access to this area by SLU hospital staff is currently restricted however the hospital strongly desires to have access open to staff. PETNET is examining solutions that would allow access to this area while maintaining compliance with the constraint specified in 10 CFR 20.1101(d). An employee entrance is located on the north side of the building, approximately 11 to 12 meters from the discharge point.

10. *Submit results of effluent released for CY 2010 and 2011 (to date), and PETNET's assessment of public dose from this data.*

    Please see Attachment D for the 2010 report on effluents. Due to issues with the capture of ^{13}N emissions both 2010 data and January through September data of 2011 were used to determine the contribution of ^{13}N for 2010. As the release of ^{13}N was greatly reduced in December 2010, effluent activity is less than 50% that of previous years, going from over 700 mCi per month down to 316 mCi on average.

While ^{13}N is still being released during the target unloading process, the entire release is accounted for as if it were ^{18}F. This is conservative because the dose conversion factor for ^{13}N is much less than that of ^{18}F (reference 10 CFR 20 Appendix B Table II).

The total activity released for 2011 as of 12/28/11 at 09:30 was 3742.3 mCi. Using COMPLY with all site-specific parameters as for the attached 2010 calculation, the annual effective dose is 7.8 mrem assuming 24 hour occupancy on the perimeter sidewalk.

11. *Explain or provide justification as to why effluent from the cyclotron is not filtered.*

During normal operations the primary source of radioactive effluent is from the chemistry module used to transform the raw PET radiochemical into the finished PET radiopharmaceutical. The chemistry modules are enclosed in shielded mini cells, which are maintained at negative pressure relative to the lab pressure. The exhaust from the enclosure passes through the filter bank and then out of the exhaust. Some ^{13}N is produced in the target during bombardment due to the presence of a ^{16}O impurity. When the target is depressurized prior to unloading, some of this ^{13}N, most likely as $^{13}N_2$, will be released. With the very early RDS-112 cyclotrons, such as the unit at this facility, some of the plumbing was not standardized. PETNET had difficulty locating the actual vent point and it was not until December 2010 that it was finally located and N-13 effluents were controlled.

Effluent releases directly from the cyclotron of ^{18}F are rare. The cyclotron tank is maintained at a high vacuum. When a target window is ruptured, the ^{18}F in water is pulled into the tank where it adheres to the metal surfaces. It also goes through the diffusion pumps and is absorbed in the pump oil. This in effect, acts as a filter for target failures.

12. *Describe the average concentration of F-18 released per day and estimated total activity released per year and submit an assessment that demonstrates that these values are in compliance with NRC regulations.*

Please see the response to item 10 above and Attachment D for information on activity released per year. Attachment D also includes the 2010 COMPLY code results. The total activity released in 2011 (as of 12/28/11) was 3742.3 mCi. Since there are approximately 260 days of operation the average daily release was 14.4 mCi. The average flow rate was 1070 ft^{3}/min, or $4.36*10^{10}$ cm^3 per day. Therefore, the average daily concentration was $3.3*10^{-7}$ $\mu Ci/cm^3$. PETNET notes that we are unaware of a regulation governing the daily effluent concentration. The annual effluent concentration for 2011 is

2.35*10-7 μCi/cm^3. PETNET intends to demonstrate compliance with the annual dose limit in 10 CFR 20.1301 via 20.1302(b)(1).

13. *Describe your program for verifying the integrity of the delivery lines that supply F-18 to the hot cells and mini-cells from the cyclotron. Describe safety procedures for changing out delivery lines that may be contaminated with F-18.*

The delivery lines are changed out on a set schedule for compliance with Good Manufacturing Practices. The delivered volume of material is closely watched. Due to the very high activity concentration any missing volume is readily evident in missing activity. The delivery lines are enclosed in PVC pipe, and embedded in concrete. The possibility for a leak into the environment is extremely remote. Typically multiple lines are pulled through at one time so that the change-over does not necessarily require removal of existing lines. In the event lines were removed, the staff waits until the next day for the ^{18}F to decay. Used lines are held in the long term waste storage for off-site disposal.

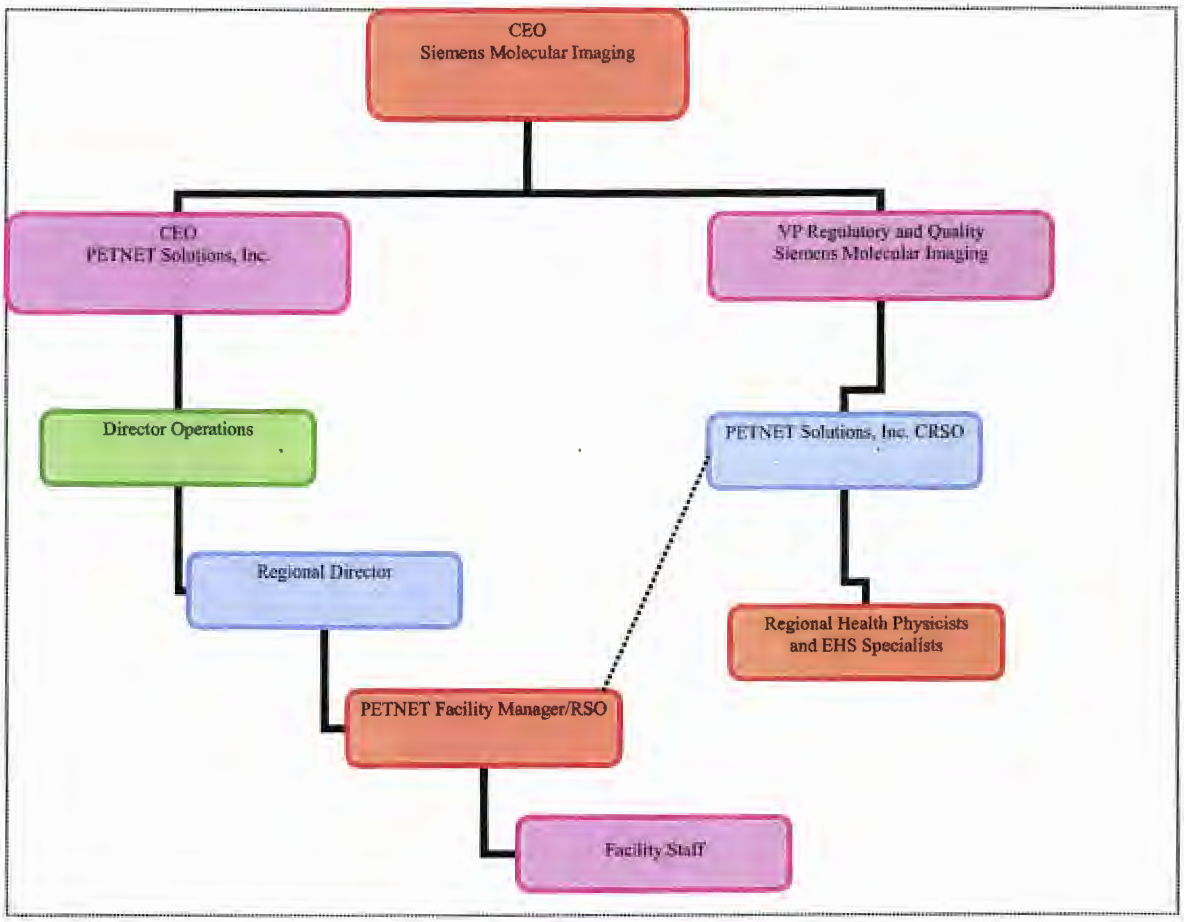
14. *Define more clearly the specific frequency for conducting both exposure rate surveys and contamination surveys.*

Per PETNET's procedure, exposure rate and contamination level surveys are performed daily in the restricted area and weekly in the unrestricted area.

15. *Submit a "Delegation of Authority" for the Corporate RSO. Also submit a delegation of authority for the facility RSO.*

We have attached a delegation of authority for the site RSO in Attachment E below. We no longer wish to list a Corporate RSO so please delete this reference.

Attachment A
Organizational Chart



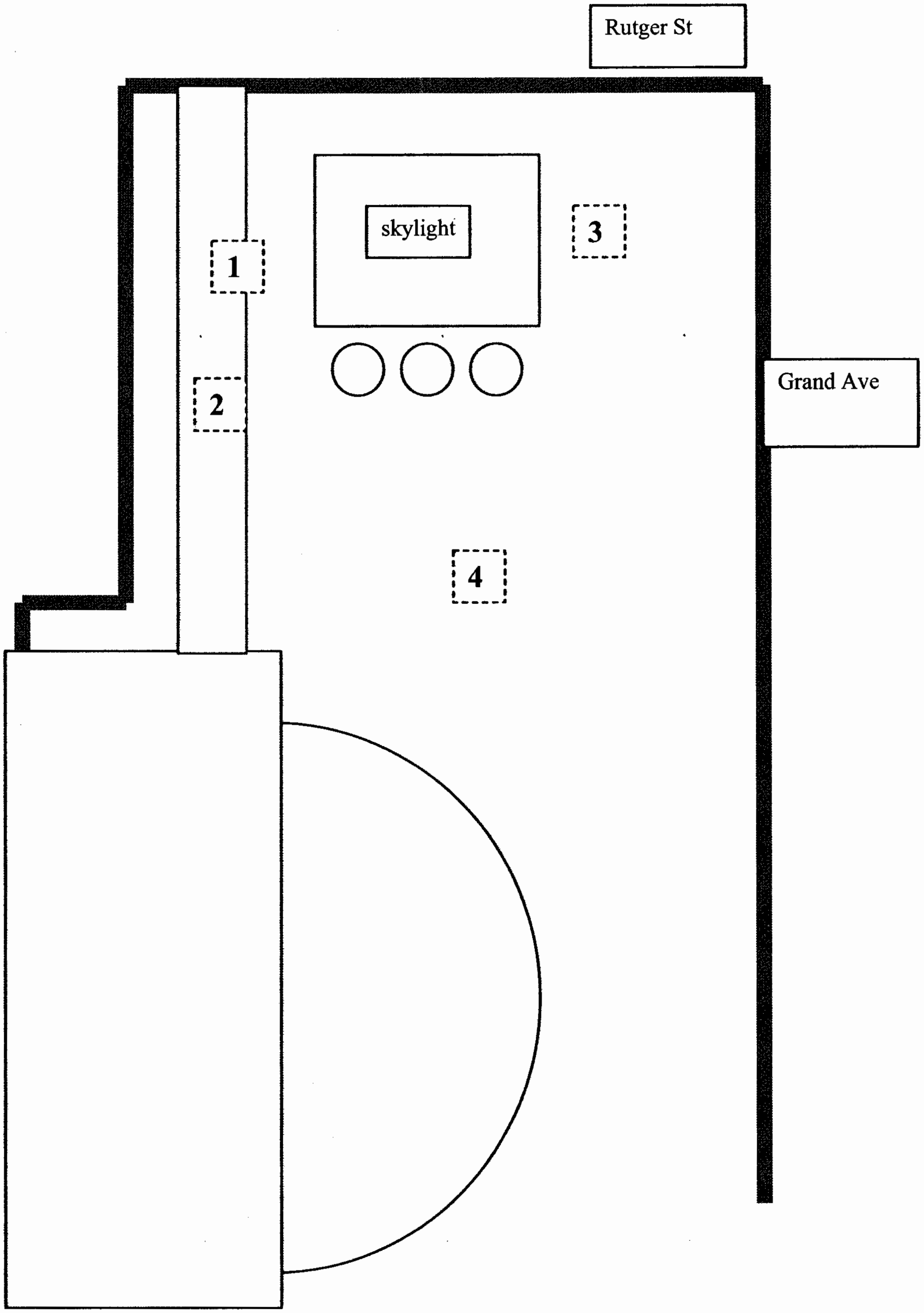
CEO
Siemens Molecular Imaging
CEO
PETNET Solutions, Inc.
VP Regulatory and Quality
Siemens Molecular Imaging
Director Operations
PETNET Solutions, Inc. CRSO
Regional Director
Regional Health Physicists
and EHS Specialists
PETNET Facility Manager/RSO
Facility Staff

Attachment B
Survey Results

Results from radiation level survey conducted on November 22, 2011. Cyclotron was running dual 45 μA beams onto target stations 3 & 4 with ^{18}O targets.
Gamma: Ludlum Model 3 & 44-38 probe S/N 88273 cal'd 3/7/2011
Neutron: Thermo ASP2e/NRD S/N 1025 cal'd 11/30/2011

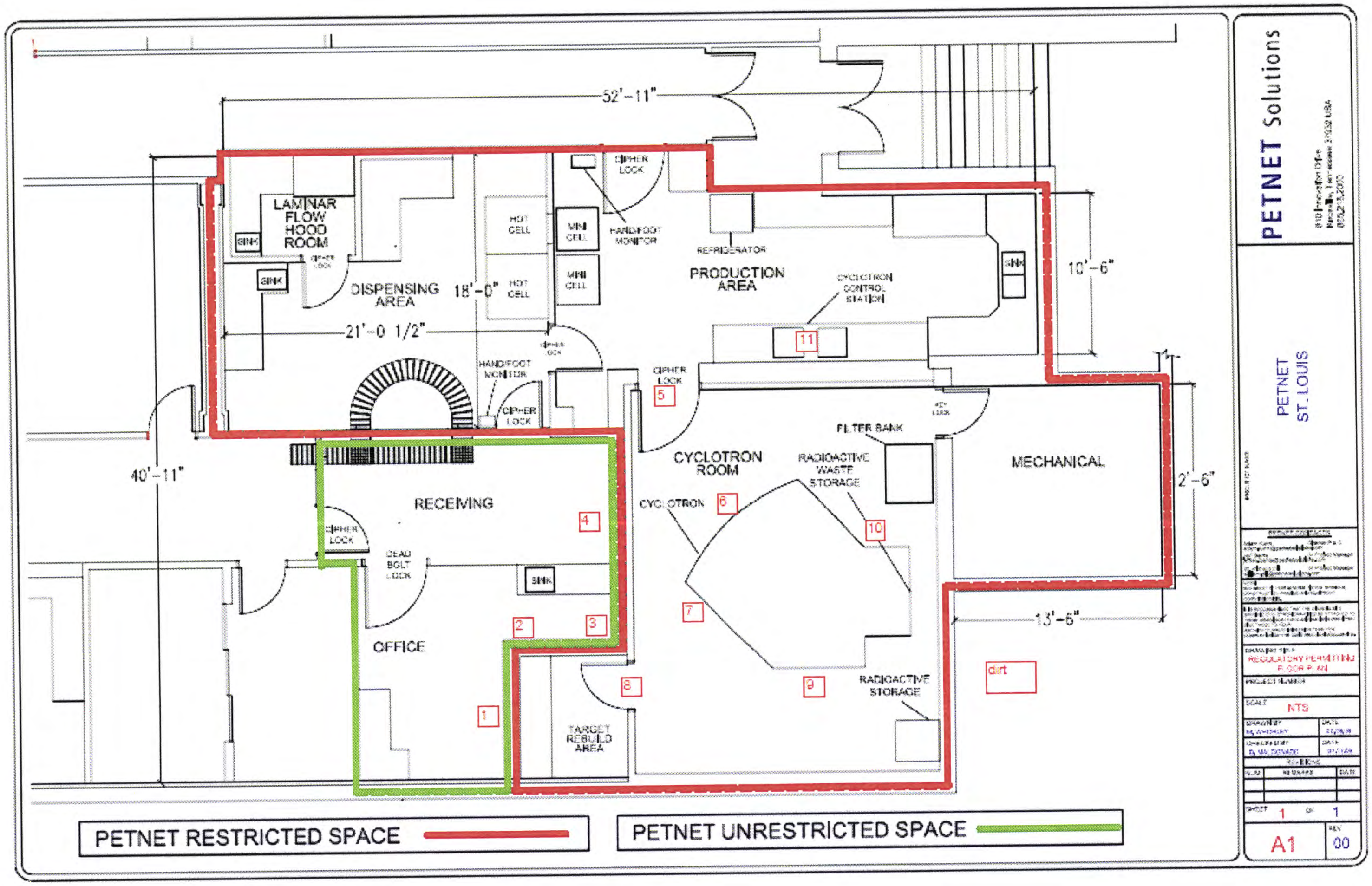
See Figure below for survey locations. Results in table include background of approximately 0.03 mR/h gamma.

Location	Gamma (mR/h)	Neutron (mrem/h)	Total (mrem/h)
1	0.03	0.054	0.084
2	0.03	0	0.03
3	0.03	0	0.03


Rutger St
skylight
1
3
2
Grand Ave
4

Survey results for inside – same conditions and instruments as above. See Figure below for survey locations

Location	Gamma (mR/h)	Neutron (mrem/h)	Total (mrem/h)	Total (mrem/year)	Classification	Annual dose w/ OF
1	0.05	0.054	0.104	135.2	controlled	33.8
2	0.4	0.109	0.509	661.7	controlled	165.425
3	0.7	0.054	0.754	980.2	controlled	245.05
4	0.3	0	0.3	390	controlled	97.5
5	2.5	0.6	3.1	4030	restricted	
6	8	1.3	9.3	12090	restricted	
7	35	0.7	35.7	46410	restricted	
8	5	0.4	5.4	7020	restricted	
9	11	1.2	12.2	15860	restricted	
10	6	2.8	8.8	11440	restricted	
11	0.05	0	0.05	65	restricted	



52'-11"
LAMINAR FLOW HOOD ROOM
SINK
SINK
DISPENSING AREA
18'-0"
21'-0 1/2"
HOT CELL
HOT CELL
MINI CELL
MINI CELL
CIPHER LOCK
HAND/FOOT MONITOR
REFRIGERATOR
PRODUCTION AREA
CYCLOTRON CONTROL STATION
SINK
10'-6"
HAND/FOOT MONITOR
CIPHER LOCK
CIPHER LOCK
CIPHER LOCK
KEY LOCK
FILTER BANK
CYCLOTRON ROOM
RADIOACTIVE WASTE STORAGE
CYCLOTRON
MECHANICAL
2'-6"
40'-11"
RECEIVING
CIPHER LOCK
DEAD BOLT LOCK
SINK
OFFICE
13'-6"
dirt
RADIOACTIVE STORAGE
TARGET REBUILD AREA
1
2
3
4
5
6
7
8
9
10
11
PETNET RESTRICTED SPACE
PETNET UNRESTRICTED SPACE
PETNET Solutions
PETNET ST. LOUIS
REGULATORY PERMITTING FLOOR PLAN
NTS
SHEET 1 OF 1
A1
00

Attachment C
Effluent Diagram

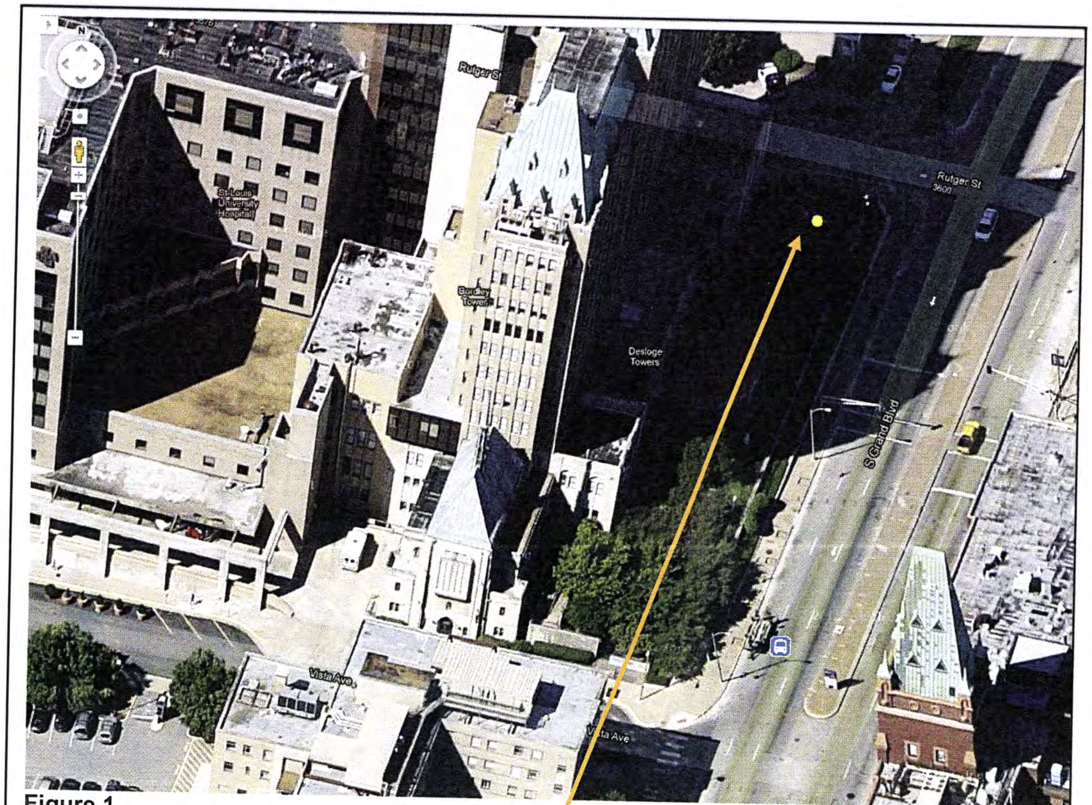
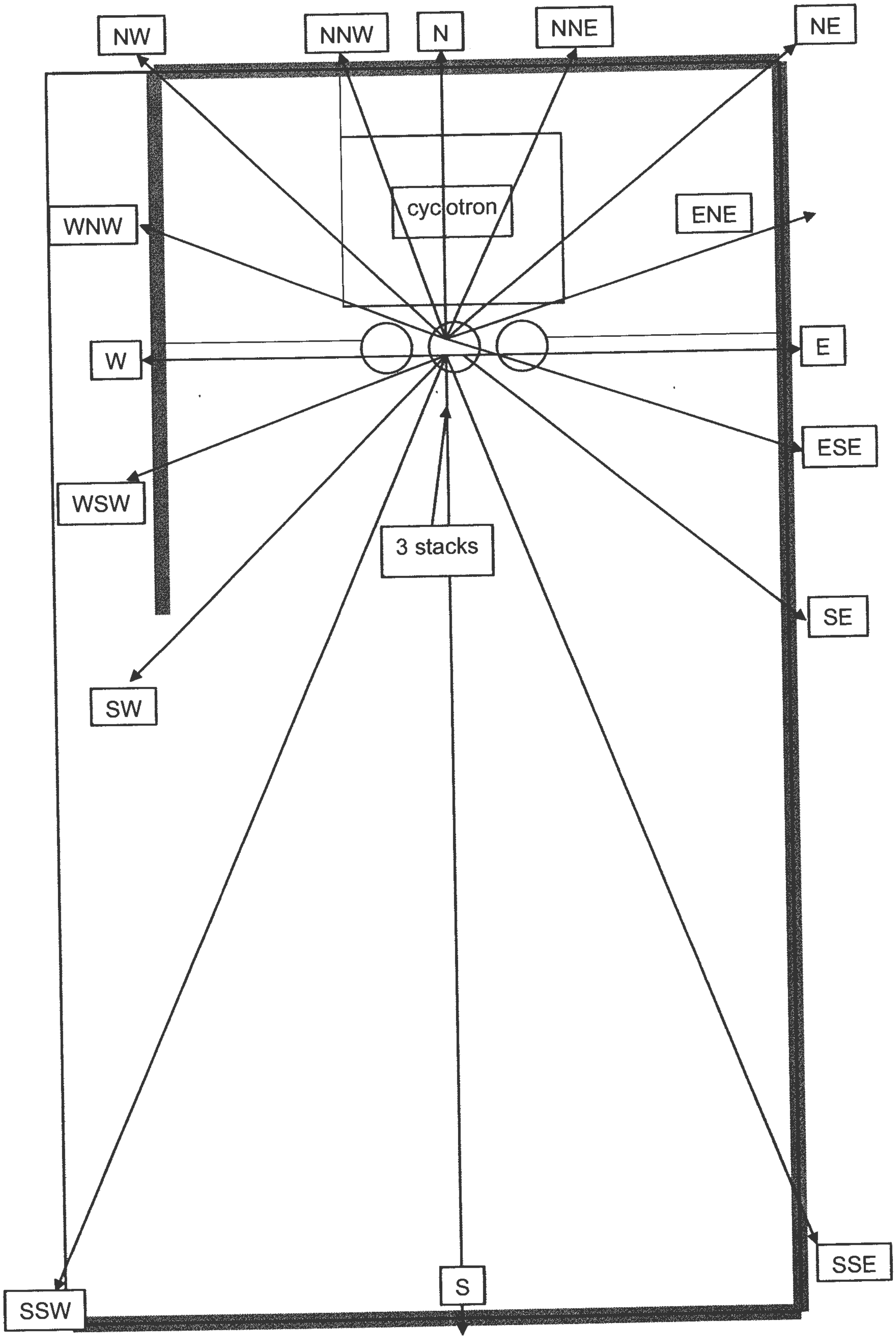

Rutger St
Rutger St
3600
St Louis University Hospital
Bordley Tower
Desloge Towers
S Grand Blvd
Vista Ave
Vista Ave
Stack discharge point

Figure 1

Figure 2



NW
NNW
N
NNE
NE
cyclotron
WNW
ENE
W
E
ESE
WSW
3 stacks
SE
SW
SSE
S
SSW

Table 1 - Distances used in COMPLY Code

Direction	Distance (m)
N	7
NNE	6.7
NE	7
ENE	9.1
E	8.2
ESE	7.6
SE	9.1
SSE	12.2
S	42.7
SSW	45.7
SW	12.2
WSW	9.1
W	8.5
WNW	9.1
NW	9.7
NNW	6.4

Attachment D
2010 Effluent Dose Calculations

PETNET St. Louis Annual Effluent Report for 2010

Prepared By:

Roger Moroney
Regional Health Physicist
PETNET Solutions, Inc.

October 26, 2011

The St. Louis PETNET Facility is located in St. Louis, MO and is a PET Radiopharmacy. The site has one RDS 112 cyclotron. The primary production isotope is ^{18}F with some ^{13}N being produced as an unintentional by-product. The site has a stack monitor, but the 2010 data was not initially usable due to complications with N-13 releases. We corrected the N-13 release issue in Dec 2010. From June to November of 2010, the monthly average release was 728.8 mCi per month. The monthly average from Jan to Sep of 2011 was 316 mCi. This gives a monthly N-13 contribution for 2010 of 412.8 mCi. Therefore the 2010 release is calculated as 3792 mCi of ^{18}F, and 4954 mCi of ^{13}N.

Level four of the COMPLY code was used to calculate the public dose from emissions of this facility. The building data was measured during a site visit. The release height was input as 3 meters. The building height was input as 1 meter. The distance to the receptors was based on estimates in each of the cardinal directions using overhead photographs. The COMPLY code calculated an annual dose, for a receptor that was continuously present, of 14.7 mrem. Since no person is continuously present in these locations, we have applied a 0.25 occupancy factor and calculated an annual dose of 3.7 mrem. This is below the 10-mrem constraint level. Thus, the facility is in compliance. A copy of the COMPLY code output is attached.

COMPLY: V1.6. 10/26/2011 7:35

40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

REPORT ON COMPLIANCE WITH

THE CLEAN AIR ACT LIMITS FOR RADIONUCLIDE EMISSIONS

FROM THE COMPLY CODE - V1.6.

Prepared by:

Prepared for:

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Washington, DC 20460

COMPLY: V1.6. 10/26/2011 7:35

SCREENING LEVEL 4

DATA ENTERED:

Nuclide	Release Rate (curies/YEAR)
F-18	D 3.792E+00
N-13	4.954E+00

Release height 4 meters.

Building height 3 meters.

The source and receptor are not on the same building.

Building width 16 meters.

Building length 52 meters.

STACK DISTANCES, FILE: stldist.dat

DIR	Distance (meters)
N	7.0
NNE	6.7
NE	7.0
ENE	9.1
E	8.2
ESE	7.6
SE	9.1
SSE	12.2
S	42.7
SSW	45.7
SW	12.2

WSW	9.1
W	8.5
WNW	9.1
NW	9.7
NNW	6.4

WINDROSE DATA, FILE: stlouis.dat

Source of wind rose data: STAR DATA FILE: STL0603.WND
Dates of coverage:
Wind rose location:
Distance to facility:

Percent calm: 0.00

Wind FROM	Frequency	Speed (meters/s)
----	---------	----------
N	0.041	4.42
NNE	0.038	3.81
NE	0.039	3.24
ENE	0.035	3.36
E	0.042	3.60
ESE	0.061	3.76
SE	0.079	3.83
SSE	0.084	4.66
S	0.110	4.85
SSW	0.053	4.52
SW	0.054	4.13
WSW	0.061	4.19
W	0.079	4.03
WNW	0.101	5.38
NW	0.075	5.32
NNW	0.047	4.73

Distance from the SOURCE to the FARM producing VEGETABLES is 1000 meters.

Distance from the SOURCE to the FARM producing MILK is 1000 meters.

Distance from the SOURCE to the FARM producing MEAT is 1000 meters.

NOTES:

The receptor exposed to the highest concentration is located
12. meters from the source in the SW sector.

He gets his VEGETABLES from a farm located
1000. meters from the source in the N sector.

He gets his MEAT from a farm located
1000. meters from the source in the N sector.

He gets his MILK from a farm located
1000. meters from the source in the N sector.

Input parameters outside the "normal" range:

None.

RESULTS:

Effective dose equivalent: 14.7 mrem/yr.

*** Failed at level 4.

This facility is NOT in COMPLIANCE.

Please send this report to your regional EPA office.

You may contact your regional EPA office to determine further action.

********** END OF COMPLIANCE REPORT **********

Attachment E
RSO Delegation of Authority

PETNET Solutions

To: Rita Gentilcore, Radiation Safety Officer
From: Ian Turner, PETNET Chief Executive Officer
Subject: Delegation of Authority

You, Rita Gentilcore, have been appointed Radiation Safety Officer for the PETNET facility located in St Louis, Missouri and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations.

You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety.

You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the State Radiation Protection Agency or the Nuclear Regulatory Commission at any time.

It is estimated that you will spend 10 hours per week conducting radiation protection activities.

[signature] 11-2-11
Signature of Management Representative Date

I accept the above responsibilities,

[signature] 11-2-11
Signature of Radiation Safety Officer Date

cc: John Beyer, PETNET St Louis Facility Manager
Rebecca Smith, Regional Director
Anthony Stagnolia,
April Chance, PETNET Corporate Radiation Safety Officer

From:	Null, Kevin
To:	Moroney, Roger (H USA)
Subject:	RE: 12/28/11 letter
Date:	Tuesday, January 10, 2012 7:46:48 AM

Roger, another question: How did you choose the parameters you used for running COMPLY. That is, release height = 4 meters; building height = 3 meters; building width (16 meters); building length (52 meters). Can you identify the buildings here??

From: Moroney, Roger (H USA) [mailto:william.moroney@siemens.com]
Sent: Tuesday, January 10, 2012 2:28 AM
To: Null, Kevin
Cc: Chance, April (H USA)
Subject: RE: 12/28/11 letter

Hi Kevin,

I received your voicemail also and we will respond as soon as possible. I am out of the country on business for the next two weeks but that will not delay the response.

Roger

From: Null, Kevin [mailto:Kevin.Null@nrc.gov]
Sent: Monday, January 09, 2012 2:42 PM
To: Moroney, Roger (H USA)
Subject: 12/28/11 letter

Hi Roger, I have a couple of follow-up questions concerning your 12/18/11 response for the St. Louis cyclotron location:

1. Question no. 3: I want to verify the sealed sources that you will need on the license. My understanding is that there are only two: Na-22 (E&Z RV-022-200u) and Cs-137 (E&Z Model RV-137-200u).

2. Question no. 7: Describe actions that staff will take if an alarming dosimeter activates.

3. Question no. 9: Your estimated that dose to the public from effluent release is 7.8 mrem at the sidewalk. We assume, therefore, that the dose in the restricted may exceed the 10 mrem constraint rule (20.1101(d)). Therefore, we are concerned about the exact area that will be restricted and how it will be restricted. Submit a diagram that illustrates the restricted area boundary in the garden area. Describe how the area is restricted and how PETNET staff will control the area in order to prevent SLU staff, non-occupational workers, members of the public, etc., from gaining access to the area. Confirm that PETNET will maintain the area as restricted until it receives an amendment to its NRC license authorizing its release for unrestricted use.

Please e-mail reply as soon as you can. Reference as additional information to Control Number 318795.

Thanks, Kevin

PETNET Solutions

January 17, 2012

Kevin G. Null
Materials Licensing Branch
U.S. NRC Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

Re: Additional Information for Control Number 318795 - Response to questions on NRC Radioactive Material License (production of NARM) Application for the existing PETNET facility in St. Louis, MO License # 40-32720-03; docket # 030-38230

Dear Mr. Null,

The purpose of this letter is to respond to follow up questions received via emails on January 9th, 10th and 12th regarding the NRC Radioactive Material (RAM) License (production of NARM) for the existing PETNET Solutions, Inc. facility in St. Louis, MO. The response is contained below and will include the original question.

We believe that we have provided all the information that the Commission needs to grant this request. If you have any questions, please contact me at the number below, or contact Roger Moroney at (865) 218-2595.

Sincerely,

April Chance, CHP
Manager of Radiation Protection/EHS
Molecular Technologies Division of
PETNET Solutions, Inc.
(865) 308-3887 mobile
(865) 218-6355 office
april.chance@siemens.com

att: Response to Questions

cc: Rita Gentilcore, M.S., R.Ph., Facility RSO
Roger Moroney, CHP, Regional Health Physicist

Response to Emailed Questions

3. *Submit the make and model number of the sealed sources that are listed on page 5 of your application.*

Please remove the ^{57}Co source from the list. This source belongs to the Hospital and was returned to them. As all PETNET uses are PET radionuclides that emit 511 keV photons, a lower energy dose calibrator source is not needed.

The ^{22}Na is manufactured by Eckert & Ziegler and the model number is RV-022-200U. We do not currently possess a ^{137}Cs dose calibrator source however most likely we will acquire an Eckert & Ziegler RV-137-200 source when the current ^{22}Na has decayed below a usable level.

Follow up Question
Verify the sealed sources that are needed on the license. My understanding is that there are only two: Na-22 (E&Z RV-022-200u) and Cs-137 (E&Z Model RV-137-200u).

Response
That is correct, PETNET requests only the two sources listed above. Currently the site possesses a Na-22 source as it was authorized by Missouri prior to the NARM rule. Since Na-22 has a relatively short useful life it will be replaced with the more commonly used Cs-137 source once it becomes necessary.

7. *Page 21 of the application (5th bullet): Define the alarming dosimeter set point to assure that the set point is set at a fraction of regulatory limits.*

The current PETNET procedure requires that the dose alarm is set at 80 mR, the dose rate alarm is set at 1000 mR/h, and the chirp rate is one per mR. While the dose rate alarm set point might seem high, it is based on experience and a desire to eliminate nuisance alarms.

Follow up Question
Describe actions that staff will take if an alarming dosimeter activates.

PETNET's SOP requires reporting to the RP/EHS group if a daily or weekly threshold is exceeded. The worker is also instructed to contact the site RSO and the corporate office if ALARA levels are exceeded. Method of contact, phone call or email, depends on the level of dose received. The training provided to all radiation workers includes discussions on minimizing radiation exposure through the application of time, distance, and shielding. The EPD alarm will alert them to the need to consider taking action as required.

9. *Regarding the section on page 22 entitled, "Effluent Control & Monitoring": Provide a description and diagram of the point of release of effluent from the cyclotron/pharmacy operations. Please also describe the point of release relative to the nearest air intake of the SLU hospital, entrance and exits to the hospital, and the nearest unrestricted areas.*

Please see the diagram in Attachment C. The exhaust point is in a garden area elevated approximately eight feet above street level. There are no intakes on the front side of the hospital. There are doors on the front side of the hospital that open onto an upper patio, with stairs that descend from each side down to the garden area. Access to this area by SLU hospital staff is currently restricted however the hospital strongly desires to have access open to staff. PETNET is examining solutions that would allow access to this area while maintaining compliance with the constraint specified in 10 CFR 20.1101(d). An employee entrance is located on the north side of the building, approximately 11 to 12 meters from the discharge point.

Follow up Question 1

Your estimated that dose to the public from effluent release is 7.8 mrem at the sidewalk. We assume, therefore, that the dose in the restricted may exceed the 10 mrem constraint rule (20.1101(d)). Therefore, we are concerned about the exact area that will be restricted and how it will be restricted. Submit a diagram that illustrates the restricted area boundary in the garden area. Describe how the area is restricted and how PETNET staff will control the area in order to prevent SLU staff, non-occupational workers, members of the public, etc., from gaining access to the area. Confirm that PETNET will maintain the area as restricted until it receives an amendment to its NRC license authorizing its release for unrestricted use.

Follow up Question 2

Given that the effluent release is essentially ground level, I am not sure if the use of COMPLY code is appropriate and how accurate it would be. To support COMPLY code results, can you use your calculated effluent release concentration (2.35E-7uci/cm^3; is that at the release point??) and calculate what the highest public dose would be at the restricted area boundary?

Follow up Question 3

How did you choose the parameters you used for running COMPLY. That is, release height = 4 meters; building height = 3 meters; building width (16 meters); building length (52 meters). Can you identify the buildings here??

PETNET has reexamined the dose from effluent release within the garden at the point nearest the effluent release point. The COMPLY code can handle situations where the release height is less than building height, such as when the release point is a vent on the side of a building. Please see COMPLY User Guide page 3-12. PETNET has historically treated the structure in front of the Desloge Tower and above street level as a building with the receptors located on the side walks. This structure varies in height above the street but on average is three (3) meters. The dimensions used were all based on estimates using images and an on-site assessment for the raised garden area in front of the Desloge Tower and the stack height as measured. The receptors were set on the sidewalks as PETNET originally received assurances from the Hospital that the garden was not open to access. The issue of garden access has been discussed a few times over the years. Recently the Hospital has wanted to allow access. PETNET does not control the keys to the entrances to the garden. In view of this the public dose was recalculated at the closest accessible point to the stack. This changes the calculation methodology used by COMPLY as the Source and Receptor (described in COMPLY User Guide page G-2) are considered to be on the same building. This results in a conservative calculation of the concentration of radioactivity.

Using a source to receptor distance of 4 meters, the option for the source and receptor on the same building, and all other parameters as previously used, the resulting annual effective dose is 201 mrem per year. When the source and receptor are on the same building, the wind rose is only used for the farm calculations (COMPLY User Guide page 3-35). Since the half-life of ^{18}F is too short for uptake through the food chain, the use of a wind rose has no effect on the calculation. The COMPLY codes assumes 100% occupancy. Just as for external sources of radiation it is reasonable to apply an occupancy factor to this result. The worse case estimate is a hospital staff member working 7-days per week who accesses the garden for 1.0 hour per day. Since the hospital is a 24-hour per day operation, we did not consider any differences in the time of day a person was in the garden versus the PETNET production schedule and assumed the person could be there in the early morning hours and regardless of weather conditions. This equals 365 hours per year or 4% occupancy and reducing the effective dose to 8 mrem. The COMPLY code output is attached (Report 1).

Because this is very close to 10 mrem, PETNET is investigating alternatives to reduce effluents from the facility. The Hospital will not allow a stack to be attached to the front of the Desloge Tower, and there is very little space inside for additional filtration systems. This leaves an option to replacement of the current stack with an air cannon system that will result in an effective stack height greater than 2.5 times the building height. PETNET has used the COMPLY code to model an air cannon with an effective stack height of 20 feet (Report 2). With all parameters the same, the resulting effective dose at 100% occupancy is 0.02 mrem per year. Implementation of this change would definitively eliminate any need for restrictions on entrance to the garden. The COMPLY code output is attached below. If this approach is acceptable, PETNET will proceed with installation.

COMPLY CODE Output for the two cases referenced above
Report #1 – Distances to receptor locations reduced, all other parameters are unchanged

Report #2 – Distances to receptors as above, added a 9-meter effective release height (air cannon added)

Report #1
COMPLY: V1.6. 1/10/2012 1:20

40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

REPORT ON COMPLIANCE WITH

THE CLEAN AIR ACT LIMITS FOR RADIONUCLIDE EMISSIONS

FROM THE COMPLY CODE - V1.6.

Prepared by:

Prepared for:

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Washington, DC 20460

COMPLY: V1.6.   1/10/2012   1:20

original except distances

SCREENING LEVEL 4

DATA ENTERED:

Nuclide	Release Rate (curies/YEAR)
F-18	D 3.742E+00

Release height 4 meters.
Building height 3 meters.
The source and receptor are on the same building.
Stack diameter 0.41 meters.
Distance from the source to the receptor is 4 meters.
Building width 16 meters.
Building length 52 meters.
Default volumetric flow rate from the stack not used.
Volumetric flow rate is 0.472 cu m/sec.

STACK DISTANCES, FILE: stlgard.dat

DIR	Distance (meters)
N	7.0
NNE	6.7
NE	7.0
ENE	9.1
E	8.2
ESE	7.6
SE	9.1
SSE	12.2
S	14.2
SSW	15.2
SW	4.1
WSW	6.1
W	4.3
WNW	4.6
NW	6.5
NNW	4.3

WINDROSE DATA, FILE: stlouis.dat

Source of wind rose data: STAR DATA FILE: STL0603.WND
Dates of coverage:
Wind rose location:
Distance to facility:
Percent calm: 0.00

Wind FROM	Frequency	Speed (meters/s)
N	0.041	4.42
NNE	0.038	3.81
NE	0.039	3.24
ENE	0.035	3.36
E	0.042	3.60
ESE	0.061	3.76
SE	0.079	3.83
SSE	0.084	4.66
S	0.110	4.85
SSW	0.053	4.52
SW	0.054	4.13
WSW	0.061	4.19
W	0.079	4.03
WNW	0.101	5.38
NW	0.075	5.32
NNW	0.047	4.73

Distance from the SOURCE to the FARM producing VEGETABLES is 1000 meters.

Distance from the SOURCE to the FARM producing MILK is 1000 meters.

Distance from the SOURCE to the FARM producing MEAT is 1000 meters.

NOTES:

The receptor is located on the building
4. meters from the source.

He gets his VEGETABLES from a farm located
1000. meters from the source in the N sector.

He gets his MEAT from a farm located
1000. meters from the source in the N sector.
He gets his MILK from a farm located
1000. meters from the source in the N sector.

Input parameters outside the "normal" range:

None.

RESULTS:

Effective dose equivalent: 201.0 mrem/yr.

*** Failed at level 4.

This facility is NOT in COMPLIANCE.

Please send this report to your regional EPA office.

You may contact your regional EPA office to determine further action.

********** END OF COMPLIANCE REPORT **********

Report #2

COMPLY: V1.6. 1/10/2012 12:42

40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

REPORT ON COMPLIANCE WITH

THE CLEAN AIR ACT LIMITS FOR RADIONUCLIDE EMISSIONS

FROM THE COMPLY CODE - V1.6.

Prepared by:

Prepared for:

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Washington, DC 20460

COMPLY: V1.6. 1/10/2012 12:42

StL 20 feet stack

SCREENING LEVEL 4

DATA ENTERED:

Nuclide	Release Rate (curies/YEAR)
F-18	D 3.742E+00

Release height 9 meters.

Building height 3 meters.

Stack diameter 0.41 meters.

Default volumetric flow rate from the stack not used.
Volumetric flow rate is 0.472 cu m/sec.

STACK DISTANCES, FILE: stldist.dat

DIR	Distance (meters)
N	7.0
NNE	6.7
NE	7.0
ENE	9.1
E	8.2
ESE	7.6
SE	9.1
SSE	12.2
S	42.7
SSW	45.7
SW	12.2
WSW	9.1
W	8.5
WNW	9.1
NW	9.7
NNW	6.4

WINDROSE DATA, FILE: stlouis.dat

Source of wind rose data: STAR DATA FILE: STL0603.WND
Dates of coverage:
Wind rose location:
Distance to facility:

Percent calm: 0.00

Wind FROM	Frequency	Speed (meters/s)
N	0.041	4.42
NNE	0.038	3.81
NE	0.039	3.24
ENE	0.035	3.36
E	0.042	3.60
ESE	0.061	3.76
SE	0.079	3.83
SSE	0.084	4.66
S	0.110	4.85
SSW	0.053	4.52
SW	0.054	4.13
WSW	0.061	4.19
W	0.079	4.03
WNW	0.101	5.38
NW	0.075	5.32
NNW	0.047	4.73

Distance from the SOURCE to the FARM producing VEGETABLES is 1000 meters.

Distance from the SOURCE to the FARM producing MILK is 1000 meters.

Distance from the SOURCE to the FARM producing MEAT is 1000 meters.

NOTES:

Default air temperature used (55.0 degrees F).
Default stack temperature used (55.0 degrees F).
The receptor exposed to the highest concentration is located
7. meters from the source in the N sector.
He gets his VEGETABLES from a farm located
1000. meters from the source in the N sector.
He gets his MEAT from a farm located
1000. meters from the source in the N sector.

He gets his MILK from a farm located
1000. meters from the source in the N sector.

Input parameters outside the "normal" range:

None.

RESULTS:

Effective dose equivalent: 2.0E-02 mrem/yr.

*** Comply at level 4.

This facility is in COMPLIANCE.

It may or may not be EXEMPT from reporting to the EPA.

You may contact your regional EPA office for more information.

********** END OF COMPLIANCE REPORT **********

CONVERSATION RECORD
(time) (date)

TIME	DATE
	1/25/12

VISIT X CONFERENCE TELEPHONE

F INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Roger Moroney	PETNET	865-218-2595

SUBJECT

Summary of meeting with representatives of PETNET and St. Louis University Hospital to discuss air effluent from PETNET's cyclotron production activities being released into a garden area on hospital grounds, and issues pertaining to control of access to the garden area. The visit and topics discussed pertain to C/N 318795 (application for a new cyclotron license from PETNET)

SUMMARY

List of Attendees

PETNET: April Chance, Corporate RSO; Roger Moroney, Health Physicist; Rebecca Smith, Director of Operations; Rita Gentilcore, RSO/staff pharmacist

St. Louis University Hospital: Todd Stirewalt, Associate Administrator; Jay Albin, Security Director; Jeff Dossett, Imaging Director; Hugh Robichaux, Nuclear Medicine manager, St. Louis University

St. Louis University: Mark Haenchen, Director, Office of Environmental Health and Safety/RSO; Felicity Beckfield, Associate RSO

NRC, Region III: Kevin Null, Sr. Health Physicist; Peter Lee, Health Physicist

Purpose of Meeting

To discuss issues pertaining to air effluent that is being released from PETNET's cyclotron operation into a garden area that is located at the St. Louis University hospital, and initiate a dialogue for improvements in the air effluent waste stream to keep doses ALARA, and improvements in controlling access to the garden.

Background

PETNET has been managing and operating a cyclotron and radiopharmacy at the St. Louis hospital since 2001. The cyclotron is owned by St. Louis University (SLU) and is located on the East end of the hospital, and is underground and directly beneath the university hospital garden. SLU initially operated the unit until 2001 when they signed a lease agreement with PETNET to operate and maintain the cyclotron unit for the production of radionuclides (primarily fluorine-18 (F-18)). In the lease agreement, PETNET is responsible for the safe operation and maintenance of the radiopharmacy and cyclotron.

The Energy Policy Act of 2005 redefined "byproduct material" and placed certain naturally occurring and accelerator-produced radioactive material (NARM) under NRC jurisdiction. Further, entities using the new NRC regulated material were required to apply to the NRC for a new license or an amendment to an existing license for authorization of NARM.

In 2009, PETNET applied to the NRC for a new license for the production of NARM material using the cyclotron at SLU. During the review process the NRC was concerned about the location where air effluent from cyclotron operations was being emitted, and the university's and PETNET's control of access to a garden directly above the cyclotron by members of the public.

These topics were discussed during a meeting held on January 25, 2012, at the SLU hospital, and are summarized below. PETNET and SLU representatives agreed to submit both short and long terms plans to address the issues within 90 days from date the license is issued.

Summary of Issues that PETNET and SLU will address

Short term plan will describe:

1. Improvements to the current system to control access to the garden area;
2. Improvements to the current alarming system that notifies hospital security staff when unauthorized entry to the garden area is detected;
3. The method for communicating to PETNET staff when unauthorized entry to the garden area is detected;
4. The method for training and controlling access by garden maintenance staff to assure that they are not unnecessarily exposed to air effluent; and
5. A system that will be used to measure radiation dose in the garden area and at the perimeter of the restricted area until a long term plan to address air effluent from the cyclotron is implemented.

Long term plan will describe:

A proposal for future modifications to the current air effluent system that addresses concerns over the air effluent that is deposited in the hospital garden area, as well as effluent that may enter the hospital through air intakes or opened windows.

ACTION REQUIRED

Submit both short and long term plans within 90 days of issuance of the license.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Kevin Null		1/27/12

ACTION TAKEN

SIGNATURE	TITLE	DATE

From:	Null, Kevin
To:	Moroney, Roger (H USA)
Subject:	RE: PETNET short term and long term plans for effluent
Date:	Monday, January 30, 2012 11:40:28 AM

thanks, Roger. I plan to issue the license tomorrow, so send any comments that you may have as soon as you can.

From: Moroney, Roger (H USA) [william.moroney@siemens.com]
Sent: Monday, January 30, 2012 10:09 AM
To: Null, Kevin
Cc: Lee, Peter; Chance, April (H USA)
Subject: RE: PETNET short term and long term plans for effluent

Hi Kevin,

We appreciate the additional time to develop a plan and to get monitoring underway as we discussed. I also received the email summary and we'll get that reviewed and any questions back to you as soon as possible.

Thanks,
Roger

From: Null, Kevin [mailto:Kevin.Null@nrc.gov]
Sent: Friday, January 27, 2012 9:43 AM
To: Moroney, Roger (H USA)
Cc: Lee, Peter
Subject: PETNET short term and long term plans for effluent

Hi Roger,

Hope all is well with you and your family!!

After further consideration, we are going to give PETNET 90 days to submit its short term plan to address the garden access control issues and to conduct air/dose monitoring to assess dose in the garden and at the restricted area boundary, and long term plan to address the air effluent release issues.

Today, I plan to put together (in the form of a conversation record) a summary of the issues that were discussed during the site visit on January 25 and NRC's understanding of PETNET's and the hospital's commitment to submit proposed plans to address the issues. I will e-mail this to you hopefully by COB today. Please share with hospital management as you feel necessary, and provide feedback to me whether or not you agree, and if not, please let me know where your understanding differs from NRC's.

Also, I am working on the license and hope to get it completed today and issue it early next week (Monday or Tuesday). The license will have two "added" (i.e., non-standard) license conditions. One condition will require that PETNET continue to work on securing financial assurance and submit progress reports (if necessary) at a specified frequency. At this point it appears to me that PETNET has pretty much submitted everything to NRC for review. Therefore, the "ball is in our court" and requirements for complying with the condition would kick in if we were to request that PETNET provide additional information to address, for example, deficiencies.

As we discussed on Wednesday, the other condition will require that PETNET submit plans to address issues pertaining to the air effluent released into the garden area, and access control to the garden area and assessment of dose in the garden area and at the restricted area boundary. The condition will require submittal of these plans within 90 days of the issuance of the license. The cover letter will provide more detail as to what NRC expects PETNET to address in its plans, but will essentially mirror what I send you today in the conversation record.

Kevin

RECEIVED FEB 08 2012

UNITED STATES

NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

JAN 31 2012

April Chance, CHP
Manager of Radiation Protection/EHS
Molecular Technologies
Division of Siemens Molecular Imaging
(PETNET, MIBR, Cyclotrons and Sources)
810 Innovation Drive
Knoxville, TN 37932

Dear Ms. Chance:

Enclosed is your NRC Material License No. 41-32720-03 in accordance with your request.

Please note that we have added license conditions19 and 20 to your license. License Condition19 pertains to decommissioning financial assurance (DFA) and requires that PETNET continue to work toward obtaining acceptable DFA in a timely manner. License Condition 20 was added to the license and pertains to access and air effluent control to the area adjacent to the effluent release stack.

Based on the meeting the NRC had with representatives from PETNET and St. Louis University (SLU) hospital on January 25, 2012, the NRC understands that PETNET will take short term actions to enhance access control to the area adjacent to the effluent release stack from the cyclotron which will include a plan to monitor and assess the dose in the area (commonly referred to as the "garden"), and a long term goal to modify the current air effluent system.

The topics and content of each plan were discussed during the January 25 meeting at the SLU hospital, and are summarized below. PETNET and SLU representatives agreed to work to develop the plans, and PETNET will be required to submit the plans for NRC review within 90 days of the date of the enclosed license.

The short term plan will describe:

1. Improvements that will be made to the current system for controlling access to the garden;

2. Improvements that will be made to the current alarming system that notifies hospital security staff when unauthorized entry to the garden is detected;

3. A method for communicating to PETNET staff when unauthorized entry to the garden is detected;

4. A method for training maintenance staff who require access to the garden, and a means of controlling access to the garden to assure that maintenance staff are not exposed to air effluent; and

5. A system that will be used to measure radiation dose in the garden and at the perimeter of the restricted area until a long term plan that addresses concerns over air effluent from the cyclotron is implemented.

The long term plan will describe:

A proposal for modifications to the current air effluent system that addresses concerns over the potential contaminants in the air effluent that may be deposited in the garden area, as well as air effluent that may enter the hospital through air intakes or opened windows.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the mailing address listed on the license changes.

3. In accordance with 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license; or

b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

4. Request and obtain a license amendment before you:

   a. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   b. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   c. Change ownership of your organization.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

In accordance with 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Kevin G. Null
Materials Licensing Branch

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

Enclosures: 1. License No. 41-32720-03
2. New License Package

From:	Moroney, Roger (H USA)
To:	"Null, Kevin"
Subject:	update on monitoring efforts for PETNET St Louis (41-32720-03)
Date:	Thursday, February 09, 2012 2:09:00 PM

Hi Kevin,

Rita has received the first set of badges to put out in the garden area and patio beginning next Monday. Unfortunately the very first set showed up too late in the week. I have them on a weekly change out so that we might quickly see the results, but will consider changing them to monthly if there is nothing after a few cycles. We will have four badges in the garden area, two up on the patio, and one in the window of the doctor's office we visited. I'm a bit concerned as to varying background levels as some will be on concrete and others on the iron fence, but we'll see what the results are.

I also have a quote from HiQ for an air sampler that we plan on using for grab samples in a couple of spots in the garden and on the patio. No ETA as yet on it.

I heard you were in Dallas at the mid-year. Sorry I did not get a chance to chat as I was mainly in town to audit the PETNET facility there and attend a Sunday afternoon ANSI committee meeting on a new standard for monitoring effluents. We managed to get through 4 pages in four hours so don't hold your breath waiting for this one! At least we wrapped up in time to watch the super bowl. I also met with Lab Impex to discuss calibration options at sites where we do not have a capability to produce C-11 gas. I mentioned to them the questions Peter had on the effluent monitoring system but I have not yet received those from him.

Roger

Roger Moroney, CHP
Health Physicist
Siemens MI / PETNET Solutions
865-218-2595 (v)
865-201-7009 (m)
865-218-3018 (f)
william.moroney@siemens.com

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Attachment I

PETNET Solutions

3 May, 2012

Kevin G. Null
Materials Licensing Branch
U.S. NRC Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

Re: **Response to Condition #20 on NRC license number 41-32720-03 - PETNET facility in St. Louis, MO**

Dear Mr. Null,

The purpose of this letter is to respond to License Condition #20 of the PETNET Solutions, Inc. License # 41-32720-03 (St. Louis, MO). The response is contained below. The response is split into two separate issues for clarity. The first is controlling access to the garden area until such time as PETNET is able to demonstrate compliance with unrestricted dose limits for this area. The second is measurement and control of effluents and the associated radiation dose. The second issue requires a short-term and long-term plan. Once compliance with public dose limits can be demonstrated PETNET may apply for relief of the additional controls on access to the garden area. It is St. Louis University Hospital's (SLUH) desire to allow unrestricted access to the garden later this year.

We believe that we have provided all the information that the Commission needs to resolve this condition. If you have any questions, please contact me at the number below, or contact Roger Moroney at (865) 218-2595.

Sincerely,

April Chance, CHP
Manager of Radiation Protection/EHS
Molecular Technologies Division of
PETNET Solutions, Inc.
(865) 308-3887 mobile
(865) 218-6355 office
april.chance@siemens.com

att: Response to License Condition #20

cc: Rita Gentilcore, M.S., R.Ph., Facility RSO
Roger Moroney, CHP, Regional Health Physicist

Response to License Condition #20

Issue #1 – Control of access to Garden area

a) *Improvements that will be made to the current system for controlling access to the garden.*

The current system of controlling access to the garden is through locked doors that open onto the garden. PETNET and SLUH will ensure that these doors remain locked and verify by daily checks until such time as compliance with dose limits from effluents can be demonstrated and formally request relief from the additional controls.

Due to fire code requirements there is an emergency egress path through the garden area and out onto the sidewalk that must be maintained.

b) *Improvements that will be made to the current alarming system that notifies hospital security staff when unauthorized entry to the garden is detected.*

During the site visit by NRC staff on January 25, 2012 it was observed that opening the door allowing access to the garden did not activate the alarm at the hospital security office as expected. The alarm system was reprogrammed and before the NRC staff departed alarm operation was retested. The alarm sounded and a security officer was dispatched in short order. Operation of the alarm will be confirmed on a quarterly basis until such time as compliance with dose limits from effluents can be confirmed and relief from the additional controls formally requested.

c) *A method for communicating to PETNET staff when unauthorized entry to the garden is detected.*

PETNET will work with SLUH to implement a process whereby the security staff will notify PETNET whenever there has been an unauthorized entry into the garden. PETNET will keep a written log of such notifications until such time as compliance with dose limits from effluents can be demonstrated and formally request relief from the additional controls.

d) *A method for training maintenance staff who require access to the garden and a means of controlling access to the garden to assure that maintenance staff are not exposed to air effluent.*

PETNET will work with SLUH staff to ensure that staff requiring access to the garden will do so only after the end of production for the day until such time as these controls are no longer required.

Issue #2 – Measurement and Control of Effluents and the associated radiation dose

a) *A system that will be used to measure radiation dose in the garden and at the perimeter of the restricted area until a long term plan that addresses concerns over air effluent from the cyclotron is implemented.*

PETNET has purchased air sampling equipment that will allow the collection of grab samples at various locations in the garden and around the perimeter. Since the release of effluent is a discrete event that occurs at the same point in time during each manufacturing cycle, as opposed to a chronic release, plus the short half-life of the nuclides released, sampling would be for short periods at selected points in the garden. Each sample would be immediately analyzed. A typical release lasts around 15 to 20 minutes. Therefore sampling will begin at start of synthesis plus 10-minutes (SOS + 10), and will continue for 30-minutes. All times will be recorded and the result decay-corrected to the time of the peak as recorded on the effluent monitoring system.

The current Single Channel Analyzer (SCA) will be used to count the sample cartridge. The exact calibration geometry will be determined by experiment using the Cs-137 source at a short distance from the detector in order to minimize variations in counting efficiency due to positional changes of the sample cartridge. The calibration will be documented.

Sample points will be recorded on a map to ensure reproducibility if required. Please note however that the reproducibility referred to is sample position only, as the actual dispersion from the release point will vary depending on meteorological conditions. All results will be recorded in a spreadsheet, analyzed and a report generated summarizing the outcome.

b) *The long term plan will describe modifications to the current air effluent system that addresses concerns over the potential contaminants in the air effluent that may be deposited in the garden* *area, as well as air effluent that may enter through air intakes of opened windows.*

PETNET is opting to move directly to a long-term solution instead of a two-stage short-term to long-term fix. There are two reasonable approaches to reduce the annual dose equivalent from effluents to receptors in the garden. The first is to increase the height of the discharge point such that the plume does not impact the garden area. The second method is to reduce the activity released. PETNET has evaluated options for increasing the discharge height and the only long-term fix would be to route the effluent up to the top of the approximately 15-story Firmin Desloge building. This would be difficult to engineer in a visually appealing way given the historical significance of the building façade. The static pressure in such a long run of duct would also require a prohibitively large fan and motor to ensure adequate flow over that distance. PETNET investigated the use of an air cannon type device on the existing discharge point, but given the 15-story structure next to it a reasonably precise air dispersion calculation would be difficult.

The second approach is to reduce the activity discharged. PETNET normally does this through filtration systems however at this facility there is insufficient space to install a shielded filter system large enough to be effective. Therefore PETNET will utilize a gas collection and compression system that is common to PET facilities in Europe. This system will collect the exhaust gases from each chemistry module, compress them in a tank, and hold for decay prior to release. The system is still being designed but will be engineered to hold at least one full day's of effluent from two chemistry modules with each one performing at least three production batches. This, in combination with the existing filter system, will significantly reduce the activity discharged such that unrestricted dose levels will be met.

NRC FORM 532A (RIII)
(10-2004)

LICENSE NUMBER 41-32720-03

MAIL CONTROL NUMBER 578040

AMENDMENT ✓ TERMINATION ______ NEW LICENSE ______

This is to acknowledge the receipt of your letter/application dated 7-31-12,
and to inform you that the initial processing, which included an administrative review, has been performed.

☑ There were no administrative omissions identified during our initial review.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, which is being sent to you separately.

A copy of your action has been forwarded to our License Fee and Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER**. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, you may contact us at (630) 829-9887.

PETNET Solutions

July 31, 2012

Kevin G. Null
Materials Licensing Branch
U.S. NRC Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

Re: Amendment Request to Nuclear Regulatory Commission (NRC) Radioactive Material (RAM) License 41-32720-03 for our PETNET facility in St Louis, MO

Dear Mr. Null,

The purpose of this letter is to submit an amendment request for NRC Radioactive Material (RAM) Production License number 41-32720-03 for the PETNET Solutions, Inc. facility in St Louis, MO.

Specifically PETNET requests that the access restrictions for the balcony area contained in License Condition #20 be removed based on the data supplied in the attached report on air sampling results and area TLD badge data. Based on these results neither access restrictions to the balcony nor a long-term plan to address a reduction in effluents will be necessary. The lower garden area will remain a controlled access area and an emergency egress route. PETNET will continue to coordinate with the St. Louis University Hospital in regards to access to this area for maintenance.

As requested, PETNET placed area monitors at various locations around the balcony and garden area. These were Landauer Luxel badges and the exchange frequency was weekly. A total of 18 weeks of data was collected, but three of these weeks were discarded due to the absence of control badge correction, and another week was discarded because the badges were accidentally exposed in the lab. All other results were "Minimal" or below the detectable level for the badge. Per Landauer specifications this minimum detectable level is one mrem.

PETNET believes that sufficient information has been provided to the Agency in order to grant this request. If you have any questions, please contact me at the number below, or contact Roger Moroney at (865) 218-2595.

Sincerely,

April Chance, CHP
Manager of Radiation Protection/EHS
PETNET Solutions, Inc.
(865) 308-3887 mobile
(865) 218-6355 office
april.chance@siemens.com

cc: Rita Gentilcore, RPh, Facility RSO
Roger Moroney, Regional Health Physicist

Attachment A: Results of Air Sampling in Balcony and Garden

PETNET Solutions

Report on Ambient Air Sampling in Balcony & Garden Area at St Louis University Hospital

By Roger Moroney, CHP

6/22/2012

PETNET Solutions, Inc.
A Siemens Company

810 Innovation Drive
Knoxville, TN 37932

Tel: (800) 738-0488
Fax: (865) 218-3018

Introduction:

The US NRC has requested information on the concentration of radioactive materials from PETNET's operations in the air around the garden at the front of the Firmin Desloge Tower at St Louis University Hospital. The effluent from PETNET's radioactive materials ventilation system are discharged from a three-meter tall stack located within a fenced and landscaped garden area located on the front side of the building. This garden is bounded on the north, east, and south sides by streets and sidewalks, and by the Hospital on the west side. Please see the photo in Figure 1. The PETNET facility is located in the basement underneath the garden. This facility was designed by the Hospital in the mid-1990s. PETNET Solutions took over operation of the cyclotron and production of PET radiopharmaceuticals in 2001.

Figure 1 – Yellow circle denotes effluent release point, red box denotes deck area

As a result of NRC concerns about public dose from effluents, use of the deck area is prohibited. The Hospital has requested unrestricted access to the deck area located in the garden (see Figure 1). An emergency egress route through the garden is required per life-safety code, but does not impact compliance with public dose limits. The purpose of this study was to examine the concentration of radioactive materials on the deck level and in the garden area during synthesis of PET radiopharmaceuticals.

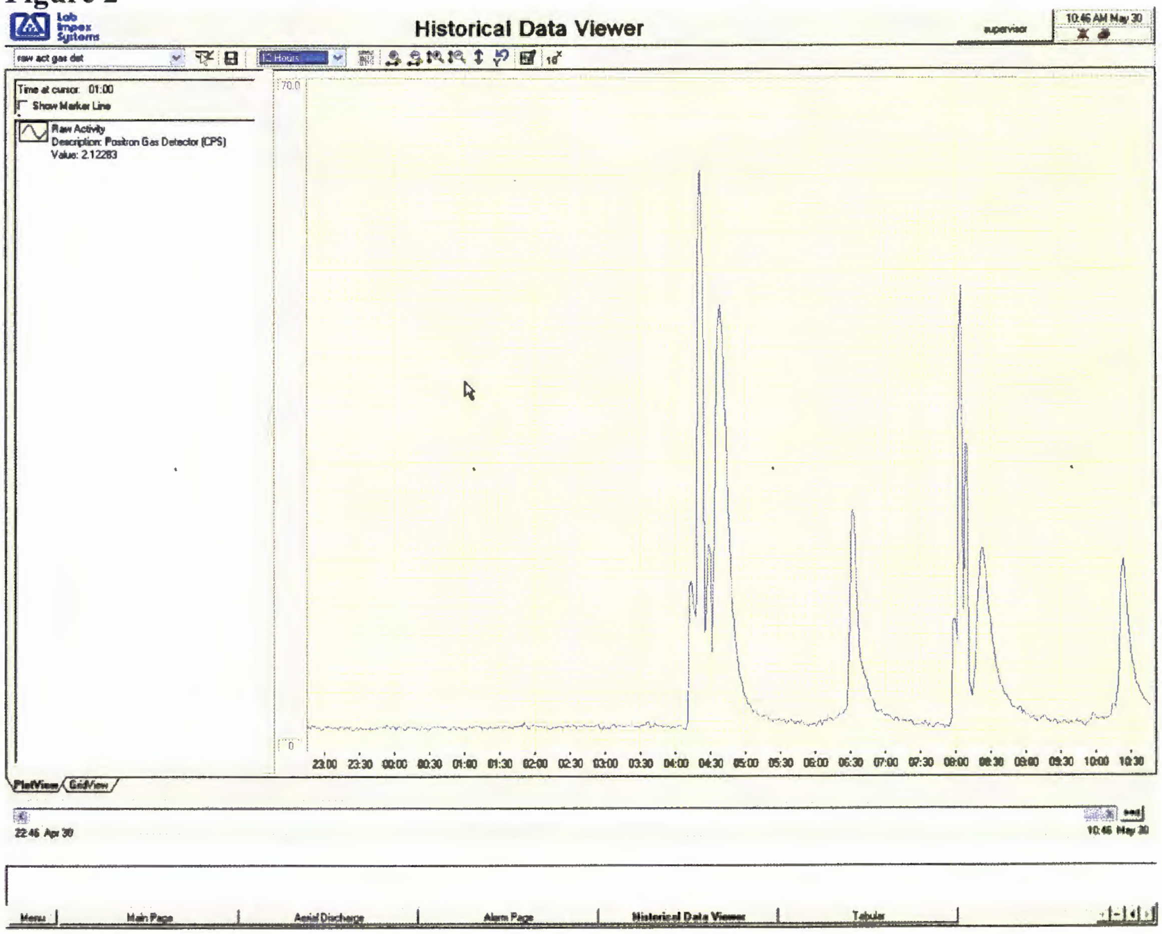
Description of Effluents:

This discussion will be primarily limited to ^{18}F since this site only produces ^{18}F-labeled radiopharmaceuticals. There are two main sources of radioactive effluent from the production of PET radiopharmaceuticals, the cyclotron itself and the radiopharmaceutical chemical synthesis process. With the cyclotron effluents are generated from target failures or from target venting prior to delivery of the material. In the case of a target failure, only those taking place after at least 30 minutes of bombardment would result in a release of activity. Most failures occur within a few minutes after beginning bombardment. A failure of the target window results in the contents of the target entering the cyclotron tank and being subsequently drawn into the vacuum system. Most of the activity will be retained in the diffusion pump oil. Both the desired ^{18}F and the unintentional byproduct of ^{13}N (from the target material impurity) will be present. The ^{13}N activity produced will be dependent on the ^{18}O enrichment level and the chemical form seems to depend on the length of bombardment. Nitrates/nitrides are produced initially and $^{13}N_2$ is produced later in bombardment. Some ^{13}N may also be released during the target unloading process, however PETNET utilizes bags to collect this effluent within a shielded enclosure.

Effluents from the chemistry occur primarily during the addition of the precursor (mannose for FDG and AV-105 for Amyvid) to the dry fluoride ion. The chemical form is believed to be hydrofluoric acid. Through experiment PETNET has determined that approximately 1.7% of the activity delivered to the chemistry module would be released in the absence of any effluent controls during production of the most common biomarker - ^{18}FDG.

Both effluent source terms result in sharp spike releases and not a chronic, low-level release. The ^{13}N release is typically only a few minutes in duration, while the release of ^{18}F may take place over 30 to 45 minutes, although the bulk of the release occurs in 10-15 minutes. Figure 2 shows a typical release profile from the site in St. Louis over several chemistry runs. The first and third releases are from FDG chemistry, and the second and fourth releases are from different biomarker chemistry.

Figure 2



Sampling Protocol (Equipment, Placement, Calibration)

The sampling approach chosen was to use a high volume air sampler coupled with an inline particulate paper filter and a charcoal canister. The air sampler is a model CF-901 from Hi-Q Environmental Products. The particulate filter is a two-inch diameter borosilicate glass fiber paper. The charcoal canister is a TC-12 TEDA-impregnated carbon packaged in a two and one quarter inch diameter by one-inch tall cartridge. The air sampler was calibrated at the factory to the ANSI/NCSL Z540-1-1994 standard for flow rate calibrations.

The collection efficiency for ^{18}F using this method was determined by experiment to be nearly 100%. See <u>Report on Collection Efficiency for $H^{18}F$ on TEDA-impregnated Activated Carbon Cartridges</u> attached at the end of this report.

Two sampling locations were selected to represent the most conservative location that Hospital personnel would likely access. Point 1 was on the balcony railing closest to the discharge point and slightly off-axis. Point 2 was almost directly below Point 1 at the edge of the raised garden area. Given the effluent is discharged via a 90-degree bend in the stack, as opposed to a more standard vertical release, these were deemed the most likely positions to receive the highest effluent concentration. It should be noted that only the balcony area is being considered for unrestricted access, the lower garden area would remain restricted except in the case of an emergency evacuation.

The winds at the time of the first sample collection on May 30 were from the north at 8 mph. By the time of the last sample of the day the wind speed had dropped but remained from the north. Please see Figures 3 and 4 for photos of the air sampler placement in relation to the discharge point.

Figure 3 – Sample Point 1

Figure 4 – Sample Point 2

Sample collection time was initially 30 minutes, but was lengthened to 45 and finally 60 minutes after examination of the release profiles from this site. Samples were counted immediately following collection. Data recorded during the sample collection include start and stop times, flow rates at start and stop and count start time for each sample. Additionally, the wind direction and speed from the internet, was recorded at least once each day.

Samples were counted on a Ludlum Model 2200 scaler connected to a Ludlum Model 203 NaI Scintillation detector. The system was calibrated for efficiency using a custom-made Eckert & Ziegler calibration source. The source activity was 5.033 μCi of ^{137}Cs (as of 15 October 2011) distributed in the carbon and placed into the cartridge. To reduce counting errors due to slight differences in placement of the cartridge, the sample distance off the face off the detector was increased by approximately 1.75 inches (Figure 5). The standard PETNET quarterly SCA calibration form was used to record counts and calculate a calibration factor. The factor was found to be 0.56%.

Figure 5

Results

Air samples were collected over the period of May 30 to June 1 2012 during chemical synthesis. Standard parameters recorded were the start and stop times of the sample, flow rates at beginning and end, and the times for each sample count along with the results. Since the release can potentially vary depending on the type of chemistry and the initial starting activity, the biomarker and its yield were also recorded. Activity calculations were decay-corrected back to the mid-point of the sample period, and the average flow rate was determined by averaging the start and stop flow rates. Please see Table 1 for a summary of the results. The complete data sheets are included as an appendix to this report.

Table 1

Date	5/30/2012	5/30/2012	5/30/2012	5/30/2012	5/31/2012	6/1/2012
Sample # (Biomarker)	Sample 1 (FDG)	Sample 2 (AV45)	Sample 3 (FDG)	Sample 4 (AV45)	Sample 1 (FDG)	Sample 1 (AV45)
Location	balcony	balcony	balcony	balcony	garden	balcony
Conc. (μCi/ml)	3.131E-08	3.193E-09	1.322E-09	2.907E-10	6.838E-09	2.337E-10
Targets	dual	dual	single	dual	dual	dual

The 10 CFR 20, Appendix B, Table 2 effluent values for ^{18}F is $1x10^{-7}$ μCi/cm^3. This concentration, if inhaled continuously over a year, would result in a total effective dose equivalent (TEDE) of 50 mrem. The contribution of the two different biomarkers was considered separately due to the difference in measured concentrations. For FDG, the number of hours per week when this concentration would be present was divided into the number of hours in a week, resulting in a value of 0.089. For AV45 production the value is 0.06. The estimated number of syntheses per day is three FDG and two AV45. Calculation of the TEDE is as follows:

$$\text{TEDE} = \frac{\text{release hours}}{\text{year}} * \left(\frac{\text{highest measured effluent concentration } (\mu\text{Ci/mL})}{\text{Table 2 limit } (\mu\text{Ci/mL})} \right) * 50 \text{ mrem}$$

$$\text{TEDE}_{\text{FDG}} = \left[\frac{0.089}{\text{year}} * \left(\frac{3.131\text{E}-8 (\mu\text{Ci/mL})}{1\text{E}-7 (\mu\text{Ci/mL})} \right) * 50 \text{ mrem} \right] = 1.39 \text{ mrem}$$

$$\text{TEDE}_{\text{AV45}} = \left[\frac{0.06}{\text{year}} * \left(\frac{3.193\text{E}-9 (\mu\text{Ci/mL})}{1\text{E}-7 (\mu\text{Ci/mL})} \right) * 50 \text{ mrem} \right] = 0.1 \text{ mrem}$$

Therefore the $\text{TEDE}_{\text{Total}}$ from effluents to a person continuously present on the balcony would be approximately 1.5 mrem.

Discussion

One of the limitations of this report is the small number of samples. While the wind conditions were judged to be nearly worse case as far as directing the effluent towards the sample location, it is conceivable that a wind blowing from the west would create a low pressure zone in the building wake that would tend to trap the effluent in the garden and balcony area. These conditions could result in an increased concentration at the sample points. However, given the very low fraction of a year in which effluent is present, even a two times increase in concentration due to building wake effects would still only result in a calculated TEDE of 3 mrem.

PETNET will collect additional samples over the next six months to monitor changes in the measured concentration.

Sample Results

location	5/30/2012 Sample 1 (FDG) balcony	5/30/2012 Sample 2 (AV45) balcony	5/30/2012 Sample 3 (FDG) balcony	5/30/2012 Sample 4 (AV45) balcony	5/31/2012 Sample 1 (FDG) garden	6/1/2012 Sample 1 (AV45) balcony
start time	4:14	6:05	8:03	9:55	7:00	5:01
stop time	4:48	6:50	8:38	10:38	7:30	6:01
net time	0:34	0:45	0:35	0:43	0:30	1:00
mid-point	4:31	6:27	8:20	10:16	7:15	5:31
start flow (ft^3/min)	8	8	8	8	8	8
stop flow (ft^3/min)	8	8	8	8	8	8.25
ave flow (ft^3/min)	8	8	8	8	8	8.125
total flow (ft^3)	272.00	360.00	280.00	344.00	240.00	487.50
total flow (ml)	7702182.384	10194064.92	7928717.16	9740995.368	6796043.28	13804462.91
start bkg count	4:53	6:54	8:40	10:44	7:34	6:07
background	297	213	332	288	546	166
paper	325	280	365	332	543	N/A
net paper	28	67	33	44	-3	N/A
decay-corrected to midpoint	31.56	81.45	37.43	52.49	0.00	N/A
paper act (μCi)	0.001113441	0.002873536	0.001320563	0.001851767	0	N/A
cartridge	6257	905	561	311	1700	238
start	4:55	6:58	8:45	10:46	7:37	6:09
net cartridge	5960	692	229	23	1154	72
decay-corrected to midpoint	6803.05	841.25	259.75	27.78	1317.23	91.48
cart act (μCi)	0.240009024	0.029678911	0.009163908	0.000980243	0.046471546	0.003227206
concentration (μCi/ml)	3.13057E-08	3.19327E-09	1.32234E-09	2.90731E-10	6.83803E-09	2.3378E-10
Chemistry Yield	84%	36%	86%	14%	86%	38%
targets	dual	dual	single	dual	dual	dual

Report on Collection Efficiency for $H^{18}F$ on TEDA-impregnated Activated Carbon Cartridges

Introduction

The use of TEDA-impregnated activated carbon cartridges has been the standard air sampling technique for uses of I-125 and I-131 sodium iodide solutions for decades. It involves pulling air to be sampled through a metal cartridge holder with one cartridge in the holder. A pump sampling at a nominal 10 L/minute pulls the air to be sampled through the cartridge. A rotometer monitors the flow rate at the start and end of a sampling period. Standard testing of methyl iodide retention is used to assign a collection efficiency for radioiodines in the TEDA carbon.

In order to use this sampling system for F-18 releases, experiments were performed that generated $H^{18}F$ gas and passed it through a series of TEDA cartridges. By comparing the activity on each successive cartridge, the collection efficiency could be determined.

These experiments were performed October 12-14, 2011 at the PETNET site in Culver City, CA. MIBR maintains a research lab at the PETNET facility. The experiments were conducted in a ventilated, shielded hotcell utilizing the Bruno chemistry boxes to automate the physical and chemical reactions to generate HF gas.

The results show a collection efficiency of 99.99% on the first carbon filter.

Experimental Set Up

^{18}O-enriched water was irradiated in a cyclotron to create $^{18}F^-$ fluoride ion in water. A sample of this water was transferred to a hot cell in the research lab, where it was entered into a automated chemistry box (the so-called Bruno box). The fluoride solution was passed through a cation exchange (QMA) cartridge where all the F^- was trapped. It was then washed off the QMA with added Kryptofix 222 (4,7,13,16,21,24-Hexaoxa-1,10-diazabicyclo[8.8.8]hexacosane) and moved to a reaction vessel. The solution was dried by heating. After the fluorine was dry, 0.5 mL of 3 N HCl was added. This creates HF, which is volatile and extremely reactive. Once the HF was generated, the valve from the closed reaction vessel was opened and helium push gas was used to drive the HF out of the reaction vial to tubing. The small $1/8^{th}$ inch (OD) tubing was placed loosely into the $3/8^{th}$ inch (ID) tubing of the sampling system. This allowed the HF to flow into the larger tubing where ambient air was also drawn in. The tubing was connected to a series of four aluminum cartridge holders each with a TEDA-impregnated activated carbon cartridge. The flow rate was 10 liters per minute throughout the test. The exhaust of the sample train was delivered into an adjacent hot cell.

The generation of HF was performed at several temperatures between 60-80°C and for two timeframes: 30 minutes and 10 minutes.

After the collection periods were complete, the sample train was disassembled and the filters were transferred to sealed plastic bags and labeled. The samples and an NIST-traceable standard were counted with a sodium iodide well counter with a single channel analyzer. Both the mid-times for the generation and for the counting were used to back decay the activities on the samples. The activity on the glass fiber filter and first carbon cartridge were compared to the activity on the second, third and fourth filter.

				Activity Trapped on Carbon Cartridge (μCi)				Collection Eff of 1st Cartridge (fraction)
Experiment	Initial Activity (mCi)	Temp of Rx Vial °C	Time of Release (min)	1	2	3	4	
1	104.8	80	30	3690.62	0.06247	0.04060	0.01562	0.999968
2	1.00	70	30	642.24	0.01022	0.00307	0.00307	0.999975
3	1.08	60	30	342.42	0.00866	0.00144	0.00866	0.999945
4	1.09	60	10	298.84	0.00276	0.00737	0.00368	0.999954

With all of the temperatures and duration times, which mimic the actual process in radiopharmaceutical manufacturing, the trapping efficiency on the first carbon filter was demonstrated to be 99.99% of the input HF gas.

Therefore, an ambient air sample collected on a TEDA-impregnated cartridge can be said to collect 99.99% of any airborne ^{18}F that may be present.

Report Date: January 10, 2012
Report By: David J. Krueger, CHP

Attachment B: Results of Area Badge Monitors in Garden

	DDE (mrem)							
Week of	Porch 1	Porch 2	Garden 3	Garden 4	Office Window	Garden 1	Garden 2	NOTES:
13-Feb								No control subtracted
20-Feb	M	M	M	M	M	M	M	
27-Feb	M	M	M	M	M	M	M	
5-Mar								No control subtracted
12-Mar								No control subtracted
19-Mar	13	12	13	lost	13	14	13	may have been exposed in lab before taking to garden
26-Mar	M	M	M	M	M	M	M	
2-Apr	M	M	M	M	M	M	M	
9-Apr	M	M	M	M	M	M	M	
16-Apr	M	M	M	M	M	M	M	
23-Apr	M	M	M	M	M	M	M	
30-Apr	M	M	M	M	M	M	M	
7-May	M	M	M	M	M	M	M	
14-May	M	M	M	M	M	M	M	
21-May	M	M	M	M	M	M	M	
28-May	M	M	M	M	M	M	M	
4-Jun	M	M	M	M	M	M	M	
11-Jun	M	M	M	M	M	M	M	

St. Louis

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

AUG 0 8 2012

RECEIVED AUG 14 2012

April Chance, CHP
Manager of Radiation Protection/EHS
Molecular Technologies Division of
PETNET Solutions, Inc.
810 Innovation Drive
Knoxville, TN 37932

Dear Ms. Chance:

Enclosed is Amendment No. 01 to your NRC Material License No. 41-32720-03 in accordance with your request.

Please note that as a result of your May 3, 2012, letter, we have approved your plans for addressing the additional access and air effluent control measures for the garden area above the cyclotron on St. Louis University Hospital property. Consequently, we have removed license condition 20 from your license.

License condition number 20 pertained to the NRC's understanding of actions that PETNET will take to address short term goals to improve control of access to the garden where radioactive air effluent is released from cyclotron operations including a plan to monitor and assess dose in the garden, and develop a long term plan to address issues regarding the current air effluent system.

It is our understanding that upon completion of the design of a gas collection and compression system to address issues pertaining to the current air effluent system, you will submit a description of the design for our review through a request for an amendment to your license.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

b. When the mailing address listed on the license changes.

3. In accordance with 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

a. When you decide to terminate all activities involving materials authorized under the license; or

b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

4. Request and obtain a license amendment before you:

a. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

b. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

c. Change ownership of your organization.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

In accordance with 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Kevin G. Null
Materials Licensing Branch

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

Enclosures: Amendment No. 01

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 01

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
	In accordance with letter dated May 3, 2012,
1. PETNET Solutions, Inc.	3. License number 41-32720-03 is **amended** in its entirety to read as follows:
2. 810 Innovation Drive Knoxville, TN 37932	4. Expiration date **January 31, 2022**
	5. Docket No. 030-38230 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Fluorine-18	A. Any	A. 10 curies
B. Carbon-11	B. Any	B. 2 curies
C. Nitrogen-13	C. Any	C. 2 curies
D. Oxygen-15	D. Any	D. 3 curies
E. Hydrogen-3	E. Liquid	E. 5 millicuries
F. Any byproduct material with atomic numbers 3 through 83; excluding Zinc-65	F. Incidentally Activated Products	F. 250 millicuries
G. Zinc-65	G. Incidentally Activated Product	G. 300 millicuries
H. Sodium-22	H. Sealed source (Eckert & Ziegler Model RV-022-200U)	H. 250 microcuries per source, 1 millicurie total possession
I. Cesium-137	I. Sealed Source (Eckert & Ziegler Model RV-137-200U)	I. 250 microcuries per source, 1 millicurie total possession

9. Authorized use:

A. through D. (1) For production, possession, or handling of radiochemicals for transfer to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

(2) For packaging and distribution of produced radiochemicals to persons authorized to receive licensed materials pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement States. This should not be distributed as a radiopharmaceutical or radioactive drug.

MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 41-32720-03
	Docket or Reference Number 030-38230
	Amendment No. 01

E. through G. For possession and storage of byproduct materials incidental to radionuclide production.

H. through I. Calibration and checking of the licensee's instruments

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 3635 Vista Ave., St. Louis, Missouri.

11. The Radiation Safety Officer for this license is Rita Gentilcore, R.Ph..

12. Licensed material shall be used by, or under the supervision of, Rita Gentilcore, R.Ph., John Beyer, R.Ph., Ranajit Bera, Ph.D., Lucas Fernandez, and Sailom Boualaphanh.

13. This license does not authorize distribution pursuant to 32.72 or 32.74; to persons exempt from licensing; or to general licensees.

14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State

B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested and the test results received.

C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 Becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

E. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 41-32720-03
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15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.

17. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days from decay-in-storage before disposal without regard to its radioactivity if the licensee:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee;

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

18. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

19. The licensee shall provide acceptable decommissioning financial assurance (DFA) as required by 10 CFR Part 30, Section 30.35. The licensee shall submit DFA progress reports to the U.S. Nuclear Regulatory Commission, Region III, Attention: Chief, Nuclear Materials Licensing Branch, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532 to update the NRC on the status of their DFA. The licensee shall submit DFA progress reports every 30 days until such time that DFA is submitted to the NRC for review. If the NRC determines that the DFA is not acceptable, the licensee shall continue to submit DFA progress reports every 30 days until acceptable DFA is provided to the NRC.

MATERIALS LICENSE **SUPPLEMENTARY SHEET**	License Number 41-32720-03
	Docket or Reference Number 030-38230
	Amendment No. 01

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    B. Application dated September 25, 2009; and

    C. Letters dated December 28, 2011, January 17, 2012, and **May 3, 2012.**

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 03 2012

By [signature]

Kevin G. Null
Materials Licensing Branch
Region III

From: Moroney Jr, Roger
Sent: Tuesday, September 04, 2012 10:07 AM
To: Gentilcore, Rita; Chance, April; Beyer, John
Subject: FW: update on NRC issues with PETNET releases and access to the garden at Firmin Deslodge

FYI

They have been patient.

From: STIREWALT, TODD1 [mailto:todd.stirewalt@tenethealth.com]
Sent: Tuesday, September 04, 2012 10:01 AM
To: Moroney Jr, Roger
Cc: DOSSETT, JEFFREY
Subject: RE: update on NRC issues with PETNET releases and access to the garden at Firmin Deslodge

Roger- thanks for the update. This needs to be resolved quickly, the hospital has been very patient awaiting the solution process by petnet. It is now September and the original goal was to open the patio in early summer. I was of the understanding that the solution was to install the gas collection and compression system is that still the solution? If so when will it be complete?

Thanks!

Todd Stirewalt
Assoc. Administrator
Saint Louis University Hospital
St. Louis, Mo. 63110
314-577-8073 p
Todd.Stirewalt@tenethealth.com

From: Moroney Jr, Roger [mailto:william.moroney@siemens.com]
Sent: Monday, September 03, 2012 10:03 AM
To: Gentilcore, Rita; STIREWALT, TODD1
Cc: Chance, April; 'Mark Haenchen'; Davila, Ramon (H USA)
Subject: update on NRC issues with PETNET releases and access to the garden at Firmin Deslodge

Hi Rita & Todd,

We have made some progress on opening access to the balcony area however the NRC remains concerned with unrestricted access to the balcony and coordinating access to the garden for maint workers. I discussed this with Kevin Null in Region III last week and the primary issue is with the potential adverse reaction from employees or visitors to airborne releases even if they are below regulatory limits. The air sampling results I performed on the balcony during the week of May 28 show that the annual radiation exposure to a person ***continuously present*** on the balcony during production would be 1.5 mrem. The annual regulatory limit for radiation exposure due to effluents is 50 mrem per year, with a further constraint on releases to 10 mrem per year. Since it is highly unlikely that anyone would be present 5 days a week, 260 days per year, the true exposure would be far lower.

I have attached a copy of the amendment request PETNET sent to the NRC a few weeks ago. Unfortunately it crossed in the mail with an earlier update to Region III that resulted in the assumption by the NRC that PETNET would install a gas collection and compression system to hold the radioactive effluent for decay prior to release. Kevin Null had not yet reviewed the July 31 letter when I called last week. He wants to see more air sample data before coming to a conclusion on this.

There are a couple of things I think we can do and be able to open the balcony pending this further work. The first is to install a gate on both sets of stairs leading down to the garden level. These would need to have an emergency egress opening bar so as not to impede exit in an evacuation. The second is to install a plate on the gate opening to Rutger street so that a person could not simply reach through the bars and unlatch the gate. Same for any gates opening to Vista if necessary. I have not actually walked over to that side myself so I am not sure if there is a similar problem.

We will need to continue to coordinate on access to the garden area by maint personnel and landscaping staff. it would be best if we could limit access to the garden until after noon to ensure all production has been completed. I realize that most of this type of work is usually done early in the morning so this could be an issue.

I plan on visiting the site later this month to complete additional air samples during the annual audit. It would be great if we could set up a meeting to discuss further and review possible solutions. Most likely this would be during the week of 17th or 24th of September, with the first week being preferable.

Thanks,
Roger

Roger Moroney, CHP
Health Physicist
Siemens MI / PETNET Solutions
865-218-2595 (v)
865-201-7009 (m)
865-218-3018 (f)
william.moroney@siemens.com

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The Science of Molecular Imaging

From:	Null, Kevin
To:	Moroney Jr, Roger; Lee, Peter
Cc:	Chance, April
Subject:	RE: PETNET St Louis air sampling issues 41-32720-03
Date:	Tuesday, September 11, 2012 4:43:39 PM

Roger, our point is that wind direction in and around the area where the effluent is released is going to be unpredictable due to surrounding building structure. We cannot be assured that during those 30 minute sampling times on May 30 and June 1, the wind and effluent was necessarily moving toward the samplers. We believe that you are sampling during the chemistry process (whether its 30 minutes, 45 minutes, or whatever...the issue is not the length of time that you are sampling). It's just that we believe more samples need to be taken over the course of several days so that you can get a good representation of varying wind direction and give the effluent a reasonable opportunity to reach the samplers.

From: Moroney Jr, Roger [mailto:william.moroney@siemens.com]
Sent: Tuesday, September 11, 2012 11:27 AM
To: Null, Kevin; Lee, Peter
Cc: Chance, April
Subject: PETNET St Louis air sampling issues 41-32720-03

Hi Kevin,

I am at an off-site team meeting and there is very poor cell reception. Just checked my voicemail and got your message. The release of F-18 only occurs during the chemistry process, hence the sample time of 30 min. In reviewing the stack monitor traces I saw the release extended closer to 45 min, so I increased the sample time accordingly. We are going back next week to collect more samples and will likely extend this to 60 min. These are discrete release events and not a chronic release, so sampling for longer than 60 min would actually result in a decrease in activity concentration. In one of the submissions I included screenshots of the stack monitor trace to illustrate this.

I understand the need to shelve this request pending completion of the additional collection efficiency testing. Is there anything you need from us or would this acknowledgement be sufficient?

Roger Moroney, CHP
Health Physicist
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william.moroney@siemens.com

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From:	Moroney Jr, Roger
To:	Null, Kevin
Cc:	Chance, April; Davila Jr, Ramon; Sinanian, Tigran; Stagnolia, Anthony
Subject:	update on progress with effluent monitoring at PETNET St Louis NRC Lic #41-32720-03
Date:	Wednesday, October 03, 2012 11:19:00 AM

Hi Kevin,

Please accept this email as an update on the situation with our radioactive effluents at the PETNET St Louis facility NRC license # 41-32720-03. We conducted additional air sampling during the week of September 17. During this period we collected eight samples at various locations on the balcony and in the lower garden area, including one directly in line with the exhaust at a distance of ~9 meters. All samples were collected during synthesis of the radiopharmaceuticals, which is when releases take place. The Table 2 of Appendix B to 10CFR20 gives an effluent concentration limit of 1E-7 uCi/ml in Column 1. The highest result obtained, which was the sample taken closest to the emission point, was 1.14E-7 uCi/ml. A complete report will be sent once the data is compiled.

We are also taking steps to repeat the F-18 collection efficiency test at the higher flow rate used in the High Volume air sampler at St Louis. This work is being completed this week at our facility in Los Angeles.

PETNET and Tenet Healthcare met on September 20 to discuss the restriction on access to the balcony area (including ramifications of opening the balcony) and methods to demonstrate PETNET's positive control on access to the garden level. The St Louis University (SLU) RSO was also present as Tenet contracts Radiation Safety services from SLU. Tenet continues to request opening of the balcony level for hospital employees, visitors, and patients. PETNET and the SLU RSO explained the regulatory issues and potential public interest in this situation. Tenet agreed to look at improvements in securing access to the garden level from Rutgers Avenue, alarming gates to control access from the balcony to the garden level, coordination with Tenet Hospital on grounds maintenance access control, and facility maintenance access control.

PETNET has met internally on this issue to discuss the need for additional effluent controls. Originally we felt that with the air sampling results as low as they were, that additional controls were not warranted even with the uncertainties in the plume dispersion in the leeward side of the Firmin Deslodge tower. We are however revisiting this issue over the next two weeks based on our telephone conversation yesterday. Contact was previously made with two vendors of a gas compression system like those used in Europe, and with a facility in the US that was installing a similar system. The European systems were designed for much larger facilities and we are having difficulty identifying space for their installation. PETNET remains committed to ensuring compliance with all regulatory requirements and the safety of our employees, customers, and the public.

Please let me know if you have any questions.
Roger

Roger Moroney, CHP
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william.moroney@siemens.com

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From: Null, Kevin
To: Moroney Jr, Roger
Subject: RE: update on progress with effluent monitoring at PETNET St Louis NRC Lic #41-32720-03
Date: Thursday, October 04, 2012 5:35:21 PM

Hi Roger,

Regarding the sample that was taken directly in line with the exhaust..... I thought that you said it was at a distance of 9 feet, not 9 meters. We will also want sampling done at the locations all along (360 degrees) the perimeter of the restricted area (fence) of the garden to demonstrate that members of the public on the sidewalks will not receive a dose in excess of regulatory limits.

Also, I plan to draft a letter to you expressing our understanding as to what you are doing or commit to do, along with concerns that we have, etc., and possible actions that we may have to take on the license, e.g., place limits on production, etc.

Kevin

From: Moroney Jr, Roger [mailto:william.moroney@siemens.com]
Sent: Wednesday, October 03, 2012 10:20 AM
To: Null, Kevin
Cc: Chance, April; Davila Jr, Ramon; Sinanian, Tigran; Stagnolia, Anthony
Subject: update on progress with effluent monitoring at PETNET St Louis NRC Lic #41-32720-03

Hi Kevin,

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Please let me know if you have any questions.
Roger

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865-218-3018 (f)
william.moroney@siemens.com

From:	Moroney Jr, Roger
To:	Beyer, John; "STIREWALT, TODD1"; Sinanian, Tigran
Cc:	Gentilcore, Rita; Stagnolia, Anthony; "Mark Haenchen"; Middleton, Christopher; Chance, April; Felicity Beckfield; Kear, Jason; Davila Jr, Ramon
Subject:	Minutes from Telephone conference to discuss Status of PETNET work to open balcony
Date:	Friday, October 05, 2012 4:06:00 PM

On the call:
Todd Stirewalt - Tenet
Mark Haenchen & Felicity Beckfield - SLU
Tigran Sinanian, Chris Middleton, Roger Moroney - PETNET

We discussed the unexpected response from NRC on opening the balcony 24/7 based on air sampling results. Essentially the NRC feels that there is too much uncertainty with air currents in front of the Firmin Deslodge building to allow for accurate calculation of radiation exposure due to the air releases from PETNET's operations. The NRC is also now concerned with potential exposures to persons on the sidewalks adjacent to the Grand and Rutgers Avenues.

From the NRC's viewpoint the only two options to allow unrestricted access to the balcony and eliminate the control over the garden access issue is either relocating the discharge point to the roof of the Firmin Deslodge building, or effectively making the releases as close to zero as possible by installing a gas collection system that would trap and hold the effluents from the chemistry module. Please note this would not mitigate releases from the cyclotron during a target failure. While rare we would need to assess the public exposure differently.

Discussion centered around cost of the various options. A gas compression system would need to be sited on the garden level next to the current stack discharge point due to the lack of space inside. The compression tanks would require shielding, so the weight of the system would need to be determined and compared to the limits on the roof loading. Rough estimates are upwards of $250k installed for gas compression. Routing the exhaust into the building and then up to the roof internally would require locating a chase with adequate space for the ducting, engineering of the fan, and consideration of roof top air intakes. The cost was not known. Todd stated that given how late it was in the year, that he would be willing to maintain the closure over winter through April, but was going to brief Tenet executive management.

Action Items:

Tenet:
Assist in investigating the potential for routing the effluent up to the roof of the Firmin Deslodge building. Coordinate with Gary Kelley, Dir. Of Building Services.

Not specifically discussed at this meeting, but if the NRC does agree to opening the balcony between noon and midnight, then we would still need the gates to control access from the balcony steps down to the garden area. Also the gate from Rutgers onto the garden needs to be reinforced to prevent it from being opened from outside.

PETNET:
Roger: Talk to NRC regarding allowing access to the balcony between the hours of noon and ten pm. Most releases are over by 9 or 10 am but to allow for recovery after a failed run it might be necessary to go until noon. [I left a voicemail with Kevin Null this afternoon on this topic] [**Update at 3:45pm 10/05/2012** - Kevin said they would agree to this, we need to define the times, how access is controlled and monitored, and submit a letter]

Tigran/Jason: Assign a PETNET Project manager and schedule monthly (or more frequent) calls to ensure this project stays on track.

PETNET PM: Continue to work on refining cost estimate for gas compression solution and work with Tenet to develop cost for roof exit for effluents.

Not discussed at this meeting but action items from previous meeting: Draft talking points for use in case of an issue & coordinate with Tenet media relations. Coordinate with Gary Kelley, Building Services Supervisor, on grounds keeping access. Coordinate on Tenet maintenance staff. Work with SLU RSO, Mark Haenchen on training.

Please let me know if I forgot anything.

Measurement of Collection Efficiency in Activated Charcoal Cartridges for Air Samples of Volatile ^{18}F Releases from PET Radiopharmaceutical Manufacturing. D.J. Krueger, CHP, PETNET Solutions, Inc.

Abstract

Manufacture of ^{18}F radiopharmaceuticals often results in volatile compounds being generated. Typically, very expensive stack monitoring systems are used to monitor these releases. This paper discusses the use of activated charcoal cartridges impregnated with TEDA (triethylenediamine) and two separate pump systems that can be used for duct or ambient air sampling. The key to utilizing such a system is to determine the collection efficiency for the ^{18}F compounds on these cartridges. To determine the collection efficiency, $H^{18}F$ gas was generated and passed through a series of cartridges. The fraction collected on the first and subsequent cartridges is analyzed to assess the percentage collected on each cartridge. [Slides summarizing this data were presented at the 2013 Health Physics Society Mid-year Meeting in Scottsdale, AZ]

Introduction

The use of TEDA-impregnated activated carbon cartridges has been the standard air sampling technique for monitoring the volatile uses of ^{125}I and ^{131}I sodium iodide solutions for decades. It involves pulling air to be sampled through a cartridge holder containing one TEDA cartridge. Typical room air or duct air is sampled at a nominal 10 liter/minute (L/min). Environmental sampling often involves flow rates of 4-10 cubic feet/minute (110-280 L/min).

The chemical synthesis of ^{18}F-labeled compounds for positron-emission tomography (PET) scans results in releases of volatile $H^{18}F$. Typically, commercial PET drug production involves curies of ^{18}F produced in a cyclotron and processed into PET drug in an automated chemistry module. Gaseous releases are seen when the target material (^{18}O-enriched water) is pushed out of the cyclotron target to a receiving container and during certain steps in the synthesis process. A number of commercially available "PET effluent monitors" are available to monitor the releases; such monitors can cost up to $100,000. ^{18}F drug synthesis typically is performed in shielded, negative-pressure enclosures, such as hot cells. The engineering controls of negative pressure have prevented releases into production suites and room air contamination is virtually zero in such facilities.

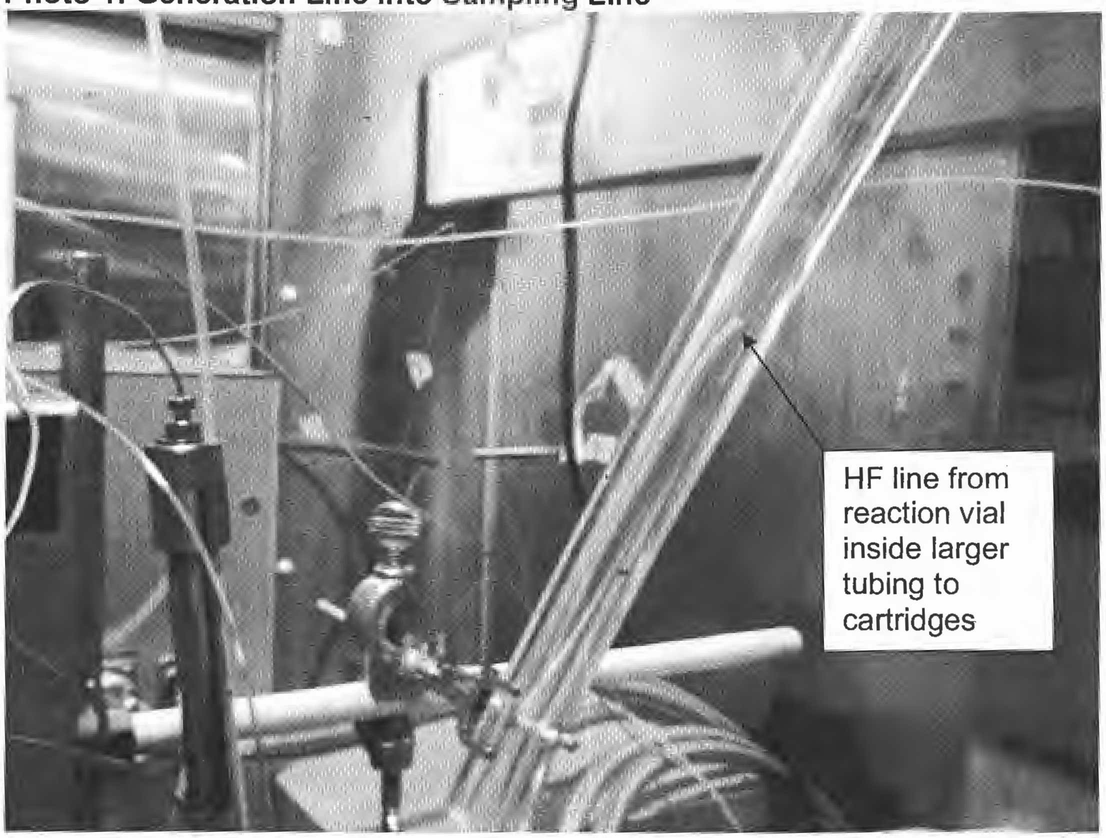
There are circumstances where room air or environmental air concentrations need to be measured or verified. The commercial stack monitors do not generally have a method of measuring ambient air. This paper discusses the use of the radioiodine sampling system for air monitoring of PET drug manufacturing effluents.

Two sets of experiments using TEDA carbon cartridges were conducted under a variety of conditions. One set was performed using a low volume flow rate (10 L/min). Multiple cartridges were set up in series to gauge the breakthrough from one filter and estimate the collection efficiency of a single cartridge that would be used for actual air sampling.

Generation of HF Gas

The production of ^{18}F involves the irradiation of ^{18}O-enriched water to create $^{18}F^-$ fluoride ion in water. In the collection efficiency experiments, a sample of the fluoride solution was transferred to a hot cell and then to an automated chemistry box. The fluoride solution was passed through a cation exchange (QMA) cartridge where the F^- was trapped. It was washed off the QMA with acetonitrile and Krypofix 222 (4,7,13,16,21,24-Hexaoxa-1,10-diazabicyclo [8.8.8] hexacosane) and moved to a reaction vial. The solution was dried by heating leaving the fluorine ion in the reaction vial. After the fluoride was dry, 0.5 mL of 3 N HCl was added. This creates HF, which is volatile and extremely reactive. Immediately before the HF was generated, the sampling pump was turned on and the valve from the closed reaction vial was opened. Helium push gas was used to drive the HF through small 1/8th inch outer diameter (OD) tubing. The small tubing was placed loosely into a 3/8th inch inner diameter (ID) tubing of the sampling system. This allowed the HF to flow into the larger tubing where ambient air was also drawn in, see Photo 1. The tubing was connected to a series of aluminum cartridge holders each with a TEDA-impregnated, activated-carbon cartridge.

Photo 1: Generation Line into Sampling Line



The generation of HF was performed at several temperatures between 60-80°C and for several durations.

General Concepts of Measuring Collection Efficiency

As HF gas is so reactive, it is extremely difficult to measure the activity presented to the collection media and measure the collected fraction directly. In the first set of experiments (low-volume runs) discussed below, only a relative measure of the starting activity was made and no attempt to measure what the fraction of the activity that was released.

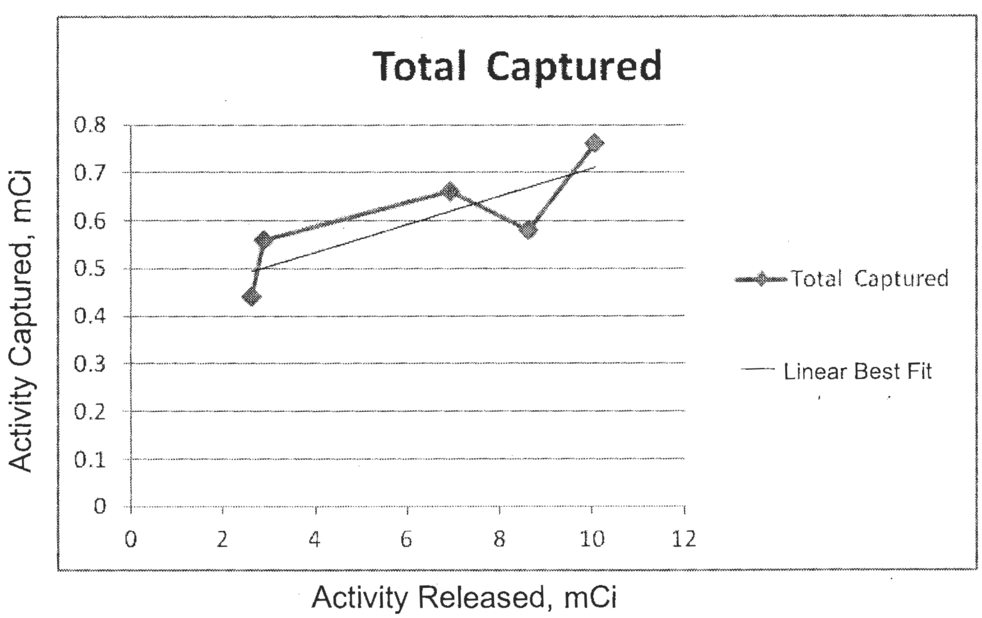
In the second set of experiments (high-volume, 1-hour runs), the activity at the beginning and end of the generation process was measured by taking the reaction vial to an active nuclear pharmacy's dose calibrator. Even this step, which supplies the activity of the generated HF gas, does not help determine the activity that was presented to the cartridges. Table 1 shows the starting and ending activity and the activity trapped on cartridges:

Table 1: Activity Released and Captured

Run	Initial Activity	Ending Activity	Activity Released	Total Captured
6	4.02	1.40	2.62	0.44
3	4.22	1.34	2.88	0.56
5	10.42	3.50	6.92	0.66
4	13.10	4.47	8.63	0.58
2	15.17	5.11	10.06	0.76

Graph 1 shows that the captured activity is somewhat related to activity released

Graph 1: Activity Captured vs. Activity Released



Collection Efficiency (CE) is typically defined as:

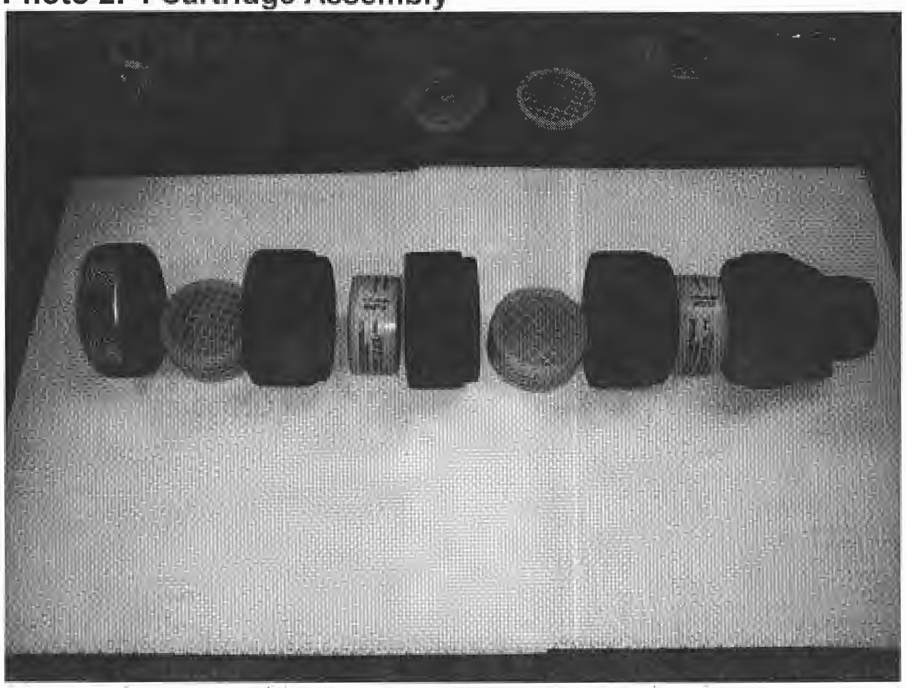
Activity collected on collection media/Activity entering collection media = CE   Eq. 1

It may appear that the data in Table 1 could be used to calculate the collection efficiency, but that conclusion is false. HF is so reactive it sticks to any surface it touches. As can be seen in Table 1, a significant portion of the starting activity remains on the reaction vial and is not released. In addition to losses in the reaction vial, significant activity sticks to the tubing, the cartridge holders and anything that comes in contact with the gas. Surveys of the tubing and holders showed them to be very contaminated, reading several mR/hr at a foot after a collection experiment. This complicates the assessment of the collection efficiency with such a reactive gas.

Instead of a mass balance assessment to calculate the collection efficiency as in Eq. 1, a simple assumption has to be made: that the activity on the first filter, relative to the total captured on all filters is a reasonable assessment of the collection efficiency. Therefore putting cartridges in series should allow calculation of a collection efficiency that is fairly accurate.

Photo 2 shows a four cartridge series in disassembled form:

Photo 2: 4 Cartridge Assembly

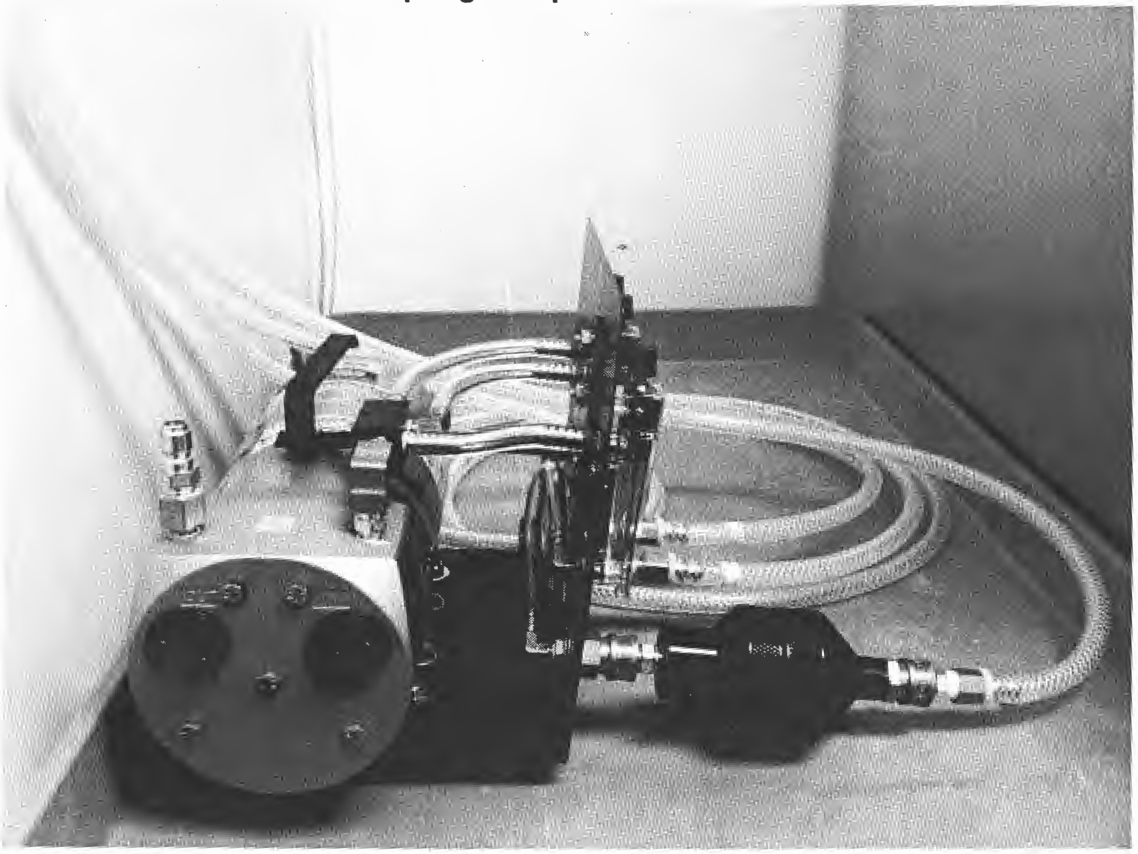


The activated cartridges used were from Hi-Q Environment Products Company in San Diego. Model TC-12, TEDA-impregnated activated carbon 8x16 mesh; 2.5"x1" plastic.

Experiment 1: Low Volume Collection Efficiency

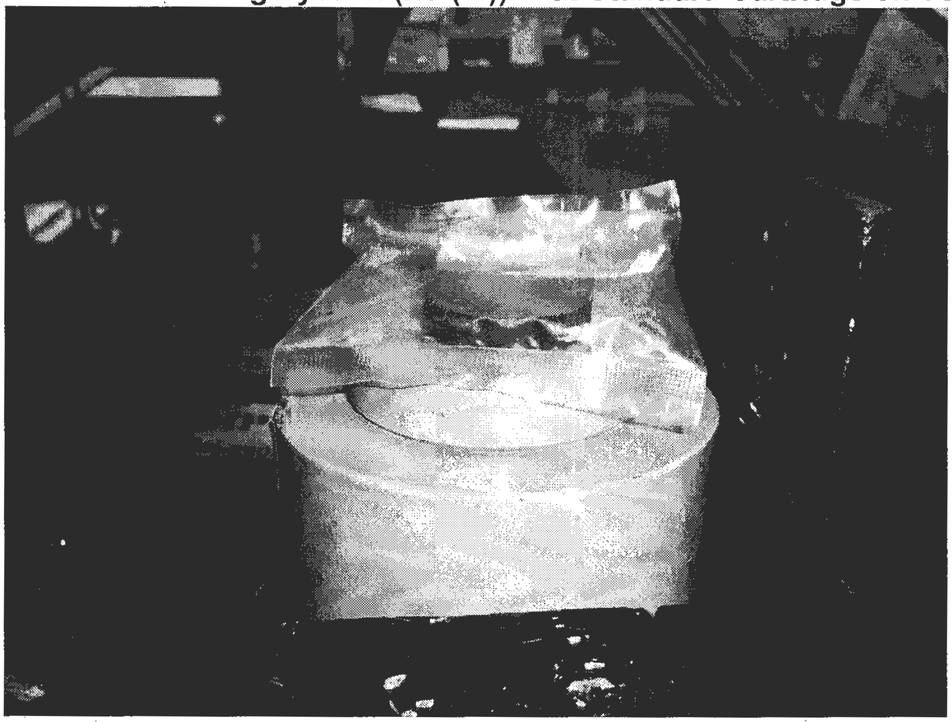
For the low volume (10 L/minute) experiments, four TEDA cartridges were connected in series, so that whatever passed through the first filter was trapped on subsequent cartridges.

Photo 3: The Low-flow Sampling Pump



After the HF gas was generated and pulled through the cartridges, the sample train was disassembled and the cartridges were transferred to sealed plastic bags and labeled. The samples and an NIST-traceable standard (^{137}Cs) were counted using a sodium iodide well counter with a single channel analyzer (Photo 3). Both the mid-times for the generation and for the counting were used to calculate the activities on the samples.

Photo 4: Counting System (NaI(Tl)) with Standard Cartridge on Top of Well



In this set of experiments, a glass fiber filter was used as is standard for cartridge air sampling. As HF reacts with glass it is collected effectively on the glass fiber filter. The activity collected on such filters is typically interpreted as particulate activity, as opposed to gaseous activity that is collected on activated carbon. Due to the nature of the gas generation process, no particulates were generated. Therefore, the activity measured on the glass fiber filter and first carbon cartridge (referred to as "1", below) were combined and compared to the total activity on the first, second, third and fourth cartridges.

$$CE = 1 / (1+2+3+4) \qquad \text{Eq. 2}$$

During these low-flow experiments, the actual activity of gas produced was not able to be determined. It was known from surveys that not all of the activity that dried in the reaction vial was released as a gas since the reaction vial had significant radiation levels after the completion of the generation/collection process. Instead, comparison of the activity on the first cartridge to the subsequent cartridges was used to determine collection efficiency.

Details of the four 10 L/minute runs are provided in Table 2 below.

Table 2: Low Volume Experiment Results

Run	Initial Activity (mCi)	Duration of Release and Collection (min)	Activity Trapped on Cartridge µCi 1	2	3	4	Collection Eff. of 1st Cartridge (fraction)
1	104.8	30	3690.6	0.06247	0.04060	0.01562	0.99997
2	1.00	30	642.24	0.01022	0.00307	0.00307	0.99997
3	1.08	30	342.42	0.00866	0.00144	0.00866	0.99995
4	1.09	10	298.84	0.00276	0.00737	0.00368	0.99995
						Average	**0.99996**
						2 sigma	**2.3E-05**

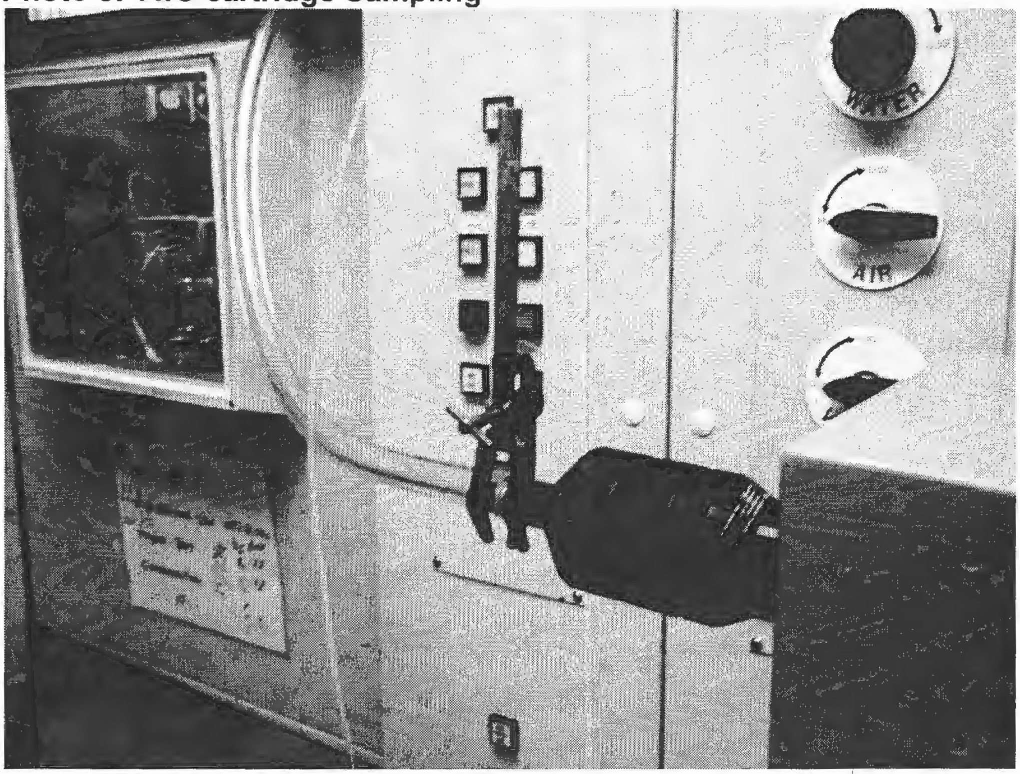
The generation of the HF gas mimics the actual process in ^{18}F radiopharmaceutical manufacturing. At 10L/min, the collection efficiency on the first carbon cartridge was demonstrated to be 99.99% of collected gas.

<u>Experiment 2: High Volume Sampling (8 cfm) for 1 Hour Collection Times</u>

The purpose of the second set of experiments was to characterize the high-volume sampling for a 1-hour sampling period. One hour represents the time during which volatiles are generated in an automated synthesis module for ^{18}F radiopharmaceuticals: from delivery of the target water to a collection vial and subsequent push to the automated chemistry module that synthesizes the ^{18}F drugs. The step in this process that has been shown to create the most volatile release is the drying and reconstitution of the fluorine ions.

In this final set of experiments, only two cartridges in series were used (Photo 5). This resulted in less restriction on flow and allowed an 8 cfm maximum flow rate. The second cartridge was used to show the percentage of breakthrough and the combined trapped activity was compared to the activity on the first cartridge to calculate collection efficiency.

Photo 5: Two-cartridge Sampling



The results for the third experiment are shown in Table 4:

Table 4: High Volume with 60 Minute Sample Time Experiment

Run	Net Activity (mCi)	Time of Release and Collection (min)	Activity Trapped on Carbon Cartridge (μCi) 1	2	Total	Collection Eff of 1st Cartridge (fraction)
2	10.06	60	709.996	51.703	761.699	0.932121
3	2.62	60	432.765	3.788	436.553	0.991323
4	8.63	60	557.145	21.827	578.971	0.962301
5	6.92	60	628.917	33.556	662.473	0.949347
6	2.88	45	529.705	25.533	555.238	0.954014
					Average	**0.957821**
					2 Sigma	**0.043466**

Therefore for a one-hour sample in the 8 cfm range the collection efficiency is 95.7%±4.3. Based on this data, a conservative collection efficiency for actual single cartridge sampling would be 91%.

Conclusions

The experiments show that the collection of HF gas on TEDA-impregnated carbon cartridges can be for determining air concentration is feasible. With low flow rates, the collection efficiency was very consistent and reproducible. The fact that the activity collected on the first cartridge is 5 orders of magnitude greater than that collected on subsequent cartridges. At 10 L/min the CE is 99.99%.

Higher sampling flow rates results in the contaminant being pulled through the carbon at a rate that is less than optimal. Regardless, the high flow rate still resulted in a CE greater than 90%.

Date: January 14, 2013
By: David J. Krueger, CHP

02-20-13

No Kevin, we will send you an official letter. This was just for your edification!

Dave

From: Null, Kevin [mailto:Kevin.Null@nrc.gov]
Sent: Wednesday, February 20, 2013 11:50 AM
To: Krueger, David J
Cc: Chance, April; Davila Jr, Ramon
Subject: RE: Paper

Thank you.

Should we use your attachments as PETNET's official response to Peter Lee's question about the collection efficiency? (see below from an e-mail that Peter sent to Roger on 9/5/12).

"Roger, the collection efficiency of 99.99% for the carbon cartridge is based on the sampling rate of 10 L/min. What's the collection efficiency for sampling rate of 226 L/min (8 cft/min) ? Please provide the data for efficiencies vs. flow rates." peter

From: Krueger, David J [mailto:david.j.krueger@siemens.com]
Sent: Wednesday, February 20, 2013 12:31 PM
To: Null, Kevin
Cc: Chance, April; Davila Jr, Ramon
Subject: Paper

Kevin,

April Chance mentioned that you are looking for a copy of my presentation. I have also included a draft of my paper that I may finalize and submit for publication. Let me know if you have any questions

David J. Krueger, CHP
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Delivering. Expanding. Advancing.
The Science of Molecular Imaging

02-28-13

All,

It was good seeing everybody today. As discussed at our late morning meeting with NRC Licensing staff today, we are scheduling a follow-up meeting on Monday, April 1, 2013 to discuss the detailed proposals that PETNET will be researching and putting together over the next 4 weeks. *(For the sake of all those involved directly, and others, I am including 2 of 7 photos I forwarded to Ramon and April early this morning that will pinpoint the relevant discussion items below.)*

A. Specific Options on the Table for Discussion:

1. **Option A:** Air Cannon - Strobic Exhaust
2. **Option B:** Additional Exterior Filter Bank with any necessary reconfiguration of exhausts

B. Additional factors to be researched and presented by PETNET, Inc. include *(but are not limited to)*:

1. Decibel levels for option A at vertical distances above exhaust approximating East windows of various floors; in addition to decibel levels at horizontal distances; and assessment of noise impact on patio area and other adjoining areas, and building occupants at all levels (as practical/necessary) so that an informed decision can be made regarding the practicality of this proposed solution.
2. Both Options:
    - Estimated dose reduction factors at garden level (taking into consideration 24/7 egress route, in addition to day-time access to patio, with the the possibility of completely unrestricted access.
    - Physical dimensions and other parameters relative to Options A and B., including Aesthetic design factors.
    - Timeline for implementation of each option, including:
        - Time from final decision on option selected to starting construction.
        - Duration of construction phase.
    - Total Cost of each option, including any aesthetic design factors.

C. Cost Allocation: Lastly, but importantly, a natural progression will be a candid discussion of cost allocation: PETNET, Inc. v. SLU Hospital. It will be ***essential*** for Tenet/SLU Hospital and PETNET, Inc. to come to agreement and resolve any potential issues on this matter so that there is a clear path forward on April 1, 2013, with no stumbling blocks and further delays on presenting to NRC our collective selection of the best/preferred option immediately following the April 1, 2013 meeting, and implementing same.

D. Meeting Date and Time: As tentatively agreed at today's meeting with NRC, we are scheduling the follow-up meeting for Monday, April 1, 2013. I am proposing a 9:00 a.m. - 11:00 a.m. time slot in the same conference room as today's meeting (Todd will assure its availability).

Please "reply all" in your responses to this email regarding your availability. *(I am available any time in the morning as early as necessary, up to 1:30 p.m.; unavailable from 1:30 p.m. to 4:15 p.m., available 4:15 p.m. or later.)* If absolutely necessary, we can push to another day that week, but I think its clear that all parties including NRC are on a very short timeline, and any significant delay would not be viewed favorably. *Please consider who will need to be present from your respective organizations in responding, and add them to the email list as appropriate when responding*.

E. Additional Air Sampling: Independent of the aforementioned meeting agenda items, PETNET will be on a parallel path of formalizing and implementing a plan for additional concurrent air sampling during peak production periods to satisfy NRC's request for same, with inclusion of dates and times, and production activity (curies) during each run, etc. presented for NRC review.

I've tried to capture most of the relevant discussion points. Please reply if there are additional.

Thanks,

- Mark

--
Mark Haenchen, M.S., J.D.
Director, Office of Environmental Health and Safety
(and Radiation Safety Officer - NRC)
Saint Louis University
Phone: (314) 977-6885
Fax: (314) 977-5560
Email: haenchen@slu.edu

ATTACHMENT B
TECHNICAL DATA

RadioFluorine Air Monitoring Worksheet
PETNET St. Louis - Balcony

TEMPLATE

Cell A2	Cell B2	Cell C2	Cell D2	Cell E2
Performed by:	Cell B3	Date:	**3/6/2013**	Sample #1 (FDG)

Counting Instrument: Single Channel Analyzer

Make: Ludlum

Model: 2200

Serial No.: 90556

	Time On	Time Off	Pump On (min)
Cell A15	3/6/13 3:00 AM	3/6/13 4:00 AM	60
	Initial Flow Rate (cfm)	**End Flow Rate (cfm)**	**Average Flow Rate (l/min)**
Cell A17	8	8	226.6

=AVERAGE(B17:C17)*28.32

Background count rate (bkg) = 300 cpm

Cell A22

Gross count rate for Cs-137 cartridge = 60793 cpm

Rp is Photon Yield Ratio = 2.28. Therefore, an F-18 standard would give off 2.28 times the photons that Cs-137 would per decay

Cell A24

Cell D24

Net count rate for standard cartridge x R_p = 138066 cpm

=(B23-B21)*(1.94/0.85)

Cs-137 Standard cartridge activity = 5 µCi on **6/1/11** **(Cal. Date)**

Time elapsed since source date= 644.00 days

decay factor= 0.96

Cell D32

Current activity for Cs-137 standard cartridge = 4.80 µCi

=B27*C31

$$F_c = \frac{\text{Net count rate for standard cartridge} \times R_p}{\text{Current activity for standard cartridge}} = 28754.20 \text{ cpm/µCi}$$

=D25/D33

Minimum Detectable Concentration (MDC) = 2.06E-10 µCi/ml

=(4.65*SQRT(B21)/D36)/B63

RadioFluorine Air Monitoring Worksheet
PETNET St. Louis - Balcony

Sampler Collection Efficiency (CE) = 91%

Gross Count Rate for sample cartridge = 1117 cpm

Gross CPM ÷ CE = 1227 cpm

=C44/C42

Net Count Rate for sample cartridge = 927 cpm

=C46-B21

t = ½ of the sampling period = 40 minutes

=(D15)*(1/2)+10

Sample Cartridge Activity in microcuries

$$\frac{\textbf{Net count rate for sample cartridge (cpm)}}{F_e\left(\frac{\text{cpm}}{\mu\text{Ci}}\right)} \times e^{\lambda t} = 4.15\text{E-02} \quad \mu\text{Ci}$$

=(C48/D36)*EXP((0.693/110)*C50)

Determine the total flow through the sampling pump

Measured avg. sample pump flow rate= 226.56 l/min

=D17

Pump-on duration = 60 min

=D15

Pump flow = (Measured sample pump flow rate) x (Pump-on duration) x (1000 ml/l)

Pump flow = 1.36E+07 ml

=C58*B60*1000

Determine the concentration of radioflourine in air

Concentration in Air Sample = Radiofluorine Activity (µCi) / Pump flow (ml) = 3.05E-09 µCi/ml

=D53/B63

RSO Review: ______________________________

Air Sampling Results
for PETNET St. Louis

Location	#	Date	Start	Stop	Total Time	Concentration (µCi/ml)
Balcony	1	5/30/2012	4:14	4:48	0:34	3.40E-08
	2	5/30/2012	6:05	6:50	0:45	3.16E-09
	3	5/30/2012	8:03	8:38	0:35	1.43E-09
	4	5/30/2012	9:55	10:38	0:43	4.78E-10
Garden	5	5/31/2012	7:00	7:30	0:30	7.65E-09
Balcony	6	6/1/2012	5:01	6:01	1:00	3.04E-10
Balcony	7	9/17/2012	3:31	4:31	1:00	3.58E-08
Garden Tree @ 9 meters	8	9/17/2012	6:30	7:30	1:00	4.98E-09
Garden Tree @ 9 meters	9	9/17/2012	8:07	9:07	1:00	1.06E-07
Garden Walkway @ 9 meters (L)	10	9/18/2012	3:39	4:39	1:00	8.37E-09
Garden Walkway @ 9 meters (R)	11	9/18/2012	6:30	7:36	1:06	2.63E-09
Balcony @ 25 meters	12	9/19/2012	6:30	7:32	1:02	2.59E-08
Balcony @ 28 meters	13	9/19/2012	8:20	9:20	1:00	3.87E-10
Sidewalk - Grand Ave @ 20 meters	14	12/18/2012	3:00	4:00	1:00	1.36E-10
	15	12/18/2012	4:00	5:00	1:00	1.95E-10
Average Concentration (µCi/ml)	16	12/18/2012	5:00	6:10	1:10	1.99E-10
1.49E-10	17	12/18/2012	6:10	7:10	1:00	1.07E-10
	18	12/18/2012	7:10	8:10	1:00	1.07E-10
Sidewalk - Vista (stairwell to garden)	19	12/19/2012	3:30	4:30	1:00	3.06E-10
Average Concentration (µCi/ml) 2.83E-10	20	12/19/2012	4:30	5:30	1:00	2.60E-10
Stairwell - To Patio from Garden	21	12/19/2012	5:40	6:40	1:00	3.44E-10
Average Concentration (µCi/ml)	22	12/19/2012	6:40	8:00	1:20	3.09E-10
2.88E-10	23	12/19/2012	8:10	9:10	1:00	2.60E-10
	24	12/19/2012	9:10	10:10	1:00	2.37E-10
Balcony	25	3/6/2013	3:00	4:00	1:00	2.73E-09
	26	3/6/2013	4:00	5:00	1:00	1.42E-10
Average Concentration (µCi/ml)	27	3/6/2013	5:00	6:00	1:00	3.76E-09
	28	3/6/2013	6:00	7:00	1:00	2.19E-10
1.29E-09	29	3/6/2013	7:00	8:00	1:00	1.32E-09
	30	3/6/2013	8:00	9:00	1:00	1.65E-10
	31	3/6/2013	9:00	10:00	1:00	6.90E-10
Egress Sidewalk	32	3/6/2013	3:00	4:00	1:00	2.01E-09
	33	3/6/2013	4:00	5:00	1:00	1.52E-11
Average Concentration (µCi/ml)	34	3/6/2013	5:00	6:00	1:00	2.38E-09
	35	3/6/2013	6:00	7:00	1:00	1.46E-10
1.04E-09	36	3/6/2013	7:00	8:00	1:00	1.32E-09
	37	3/6/2013	8:00	9:00	1:00	1.79E-10
	38	3/6/2013	9:00	10:00	1:00	1.21E-09
Garden	39	3/6/2013	3:00	4:00	1:00	1.88E-08
	40	3/6/2013	4:00	5:00	1:00	4.90E-10
Average Concentration (µCi/ml)	41	3/6/2013	5:00	6:00	1:00	4.26E-08
	42	3/6/2013	6:00	7:00	1:00	3.58E-10
1.21E-08	43	3/6/2013	7:00	8:00	1:00	1.17E-08
	44	3/6/2013	8:00	9:00	1:00	5.74E-10
	45	3/6/2013	9:00	10:00	1:00	1.05E-08

Air Sampling Results
for PETNET St. Louis

Location	#	Date	Start	Stop	Total Time	Concentration (µCi/ml)
Balcony	46	3/7/2013	3:00	4:00	1:00	4.43E-10
	47	3/7/2013	4:00	5:00	1:00	6.39E-10
	48	3/7/2013	5:00	6:00	1:00	4.88E-10
Average Concentration (µCi/ml)	49	3/7/2013	6:00	7:00	1:00	3.93E-10
	50	3/7/2013	7:00	8:00	1:00	4.58E-10
4.25E-10	51	3/7/2013	8:00	9:00	1:00	1.93E-10
	52	3/7/2013	9:00	10:00	1:00	3.63E-10
Egress Sidewalk	53	3/7/2013	3:00	4:00	1:00	2.45E-10
	54	3/7/2013	4:00	5:00	1:00	1.93E-10
	55	3/7/2013	5:00	6:00	1:00	1.93E-10
Average Concentration (µCi/ml)	56	3/7/2013	6:00	7:00	1:00	3.96E-10
	57	3/7/2013	7:00	8:00	1:00	3.45E-10
2.62E-10	58	3/7/2013	8:00	9:00	1:00	3.17E-10
	59	3/7/2013	9:00	10:00	1:00	1.44E-10
Garden	60	3/7/2013	3:00	4:00	1:00	6.08E-09
	61	3/7/2013	4:00	5:00	1:00	1.27E-08
	62	3/7/2013	5:00	6:00	1:00	6.64E-10
Average Concentration (µCi/ml)	63	3/7/2013	6:00	7:00	1:00	2.09E-09
	64	3/7/2013	7:00	8:00	1:00	3.67E-10
3.20E-09	65	3/7/2013	8:00	9:00	1:00	3.72E-10
	66	3/7/2013	9:00	10:00	1:00	1.55E-10
Balcony	67	3/8/2013	3:30	4:30	1:00	1.73E-10
	68	3/8/2013	4:30	5:30	1:00	2.86E-10
	69	3/8/2013	5:30	6:30	1:00	1.38E-10
Average Concentration (µCi/ml)	70	3/8/2013	6:30	7:30	1:00	2.14E-10
	71	3/8/2013	7:30	8:30	1:00	1.36E-10
1.78E-10	72	3/8/2013	8:30	9:30	1:00	1.23E-10
Egress Sidewalk	73	3/8/2013	3:30	4:30	1:00	1.47E-10
	74	3/8/2013	4:30	5:30	1:00	2.39E-10
	75	3/8/2013	5:30	6:30	1:00	1.34E-10
Average Concentration (µCi/ml)	76	3/8/2013	6:30	7:30	1:00	1.48E-10
	77	3/8/2013	7:30	8:30	1:00	1.62E-10
1.62E-10	78	3/8/2013	8:30	9:30	1:00	1.41E-10
Garden	79	3/8/2013	3:30	4:30	1:00	4.01E-10
	80	3/8/2013	4:30	5:30	1:00	4.52E-10
	81	3/8/2013	5:30	6:30	1:00	1.52E-10
Average Concentration (µCi/ml)	82	3/8/2013	6:30	7:30	1:00	2.25E-10
	83	3/8/2013	7:30	8:30	1:00	2.35E-10
2.70E-10	84	3/8/2013	8:30	9:30	1:00	1.52E-10

PUBLIC SIDEWALKS

#	Date	Start	End	Sampling Time	Measured (µCi/ml)	Percentage of Table 2 Limit	Daily Avg. (µCi/ml)	Annual Avg. (µCi/ml)	Annual Dose (mrem/yr)
1	12/18/2012	3:00	4:00	1:00	**1.36E-10**	0.14%	4.96E-11	1.18E-11	**0.006**
2	12/18/2012	4:00	5:00	1:00	**1.95E-10**	0.20%			
3	12/18/2012	5:00	6:10	1:10	**1.99E-10**	0.20%			
4	12/18/2012	6:10	7:10	1:00	**1.07E-10**	0.11%			
5	12/18/2012	7:10	8:10	1:00	**1.07E-10**	0.11%			
6	12/19/2012	3:30	4:30	1:00	**3.06E-10**	0.31%	9.43E-11	2.24E-11	**0.011**
7	12/19/2012	4:30	5:30	1:00	**2.60E-10**	0.26%			

=I10*50

=F10*($C$33/24)

=H10/1E-7

=F10*($C$33*$C$34*$F$34)/$C$35

Assumption 1: **8** hrs of continuous exposure in the public sidewalks areas
Assumption 2: **5** days of exposure for **52** weeks per year
Assumption 3: **8760** hours in one year

GARDEN

#	Date	Start	End	Sampling Time	Measured (µCi/ml)	Percentage of Table 2 Limit	Daily Avg. (µCi/ml)	Annual Avg. (µCi/ml)	Annual Dose (mrem/yr)
1	5/31/2012	7:00	7:30	0:30	**7.65E-09**	7.65%	2.55E-09	1.82E-09	**0.908**
2	9/17/2012	6:30	7:30	1:00	**4.98E-09**	4.98%	1.85E-08	4.38E-09	**2.192**
3	9/17/2012	8:07	9:07	1:00	**1.06E-07**	105.78%			
4	3/6/2013	3:00	4:00	1:00	**1.88E-08**	18.80%	6.27E-09	1.49E-09	**0.744**
5	3/6/2013	4:00	5:00	1:00	**4.90E-10**	0.49%			
6	3/6/2013	5:00	6:00	1:00	**4.26E-08**	42.60%			
7	3/6/2013	6:00	7:00	1:00	**3.58E-10**	0.36%			
8	3/6/2013	7:00	8:00	1:00	**1.17E-08**	11.70%			
9	3/6/2013	8:00	9:00	1:00	**5.74E-10**	0.57%			
10	3/6/2013	9:00	10:00	1:00	**1.05E-08**	10.50%			
11	3/7/2013	3:00	4:00	1:00	**6.08E-09**	6.08%	1.07E-09	1.44E-09	**0.722**
12	3/7/2013	4:00	5:00	1:00	**1.27E-08**	12.70%			
13	3/7/2013	5:00	6:00	1:00	**6.64E-10**	0.66%			
14	3/7/2013	6:00	7:00	1:00	**2.09E-09**	2.09%			
15	3/7/2013	7:00	8:00	1:00	**3.67E-10**	0.37%			
16	3/7/2013	8:00	9:00	1:00	**3.72E-10**	0.37%			
17	3/7/2013	9:00	10:00	1:00	**1.55E-10**	0.16%			
18	3/8/2013	3:30	4:30	1:00	**4.01E-10**	0.40%	8.98E-11	9.52E-11	**0.048**
19	3/8/2013	4:30	5:30	1:00	**4.52E-10**	0.45%			
20	3/8/2013	5:30	6:30	1:00	**1.52E-10**	0.15%			
21	3/8/2013	6:30	7:30	1:00	**2.25E-10**	0.23%			
22	3/8/2013	7:30	8:30	1:00	**2.35E-10**	0.24%			
23	3/8/2013	8:30	9:30	1:00	**1.52E-10**	0.15%			

Assumption 1:	**8**	hrs of continuous exposure in the garden area		
Assumption 2:	**5**	days of exposure for	**52**	weeks per year
Assumption 3:	**8760**	hours in one year		

EGRESS SIDEWALK

#	Date	Start	End	Sampling Time	Measured (µCi/ml)	Percentage of Table 2 Limit	Daily Avg. (µCi/ml)	Annual Avg. (µCi/ml)	Annual Dose (mrem/yr)
1	9/18/2012	3:39	4:39	1:00	**8.37E-09**	8.37%	1.83E-09	4.35E-10	**0.218**
2	9/18/2012	6:30	7:36	1:06	**2.63E-09**	2.63%			
3	12/19/2012	5:40	6:40	1:00	**3.44E-10**	0.34%	9.58E-11	2.28E-11	**0.011**
4	12/19/2012	6:40	8:00	1:20	**3.09E-10**	0.31%			
5	12/19/2012	8:10	9:10	1:00	**2.60E-10**	0.26%			
6	12/19/2012	9:10	10:10	1:00	**2.37E-10**	0.24%			
7	3/6/2013	3:00	4:00	1:00	**2.01E-09**	2.01%	3.46E-10	8.21E-11	**0.041**
8	3/6/2013	4:00	5:00	1:00	**1.52E-11**	0.02%			
9	3/6/2013	5:00	6:00	1:00	**2.38E-09**	2.38%			
10	3/6/2013	6:00	7:00	1:00	**1.46E-10**	0.15%			
11	3/6/2013	7:00	8:00	1:00	**1.32E-09**	1.32%			
12	3/6/2013	8:00	9:00	1:00	**1.79E-10**	0.18%			
13	3/6/2013	9:00	10:00	1:00	**1.21E-09**	1.21%			
14	3/7/2013	3:00	4:00	1:00	**2.45E-10**	0.25%	8.73E-11	2.07E-11	**0.010**
15	3/7/2013	4:00	5:00	1:00	**1.93E-10**	0.19%			
16	3/7/2013	5:00	6:00	1:00	**1.93E-10**	0.19%			
17	3/7/2013	6:00	7:00	1:00	**3.96E-10**	0.40%			
18	3/7/2013	7:00	8:00	1:00	**3.45E-10**	0.35%			
19	3/7/2013	8:00	9:00	1:00	**3.17E-10**	0.32%			
20	3/7/2013	9:00	10:00	1:00	**1.44E-10**	0.14%			
21	3/8/2013	3:30	4:30	1:00	**1.47E-10**	0.15%	5.39E-11	1.28E-11	**0.006**
22	3/8/2013	4:30	5:30	1:00	**2.39E-10**	0.24%			
23	3/8/2013	5:30	6:30	1:00	**1.34E-10**	0.13%			
24	3/8/2013	6:30	7:30	1:00	**1.48E-10**	0.15%			
25	3/8/2013	7:30	8:30	1:00	**1.62E-10**	0.16%			
26	3/8/2013	8:30	9:30	1:00	**1.41E-10**	0.14%			

Assumption 1: **8** hrs of continuous exposure in the egress sidewalk areas
Assumption 2: **5** days of exposure for **52** weeks per year
Assumption 3: **8760** hours in one year

PATIO BALCONY

#	Date	Start	End	Sampling Time	Measured (µCi/ml)	Percentage of Table 2 Limit	Daily Avg. (µCi/ml)	Annual Avg. (µCi/ml)	Annual Dose (mrem/yr)
1	5/30/2012	4:14	4:48	0:34	**3.40E-08**	34.000%	3.26E-09	7.73E-10	**0.387**
2	5/30/2012	6:05	6:50	0:45	**3.16E-09**	3.160%			
3	5/30/2012	8:03	8:38	0:35	**1.43E-09**	1.430%			
4	5/30/2012	9:55	10:38	0:43	**4.78E-10**	0.478%			
5	6/1/2012	5:01	6:01	1:00	**3.04E-10**	0.304%	1.01E-10	7.22E-11	**0.036**
6	9/17/2012	3:31	4:31	1:00	**3.58E-08**	35.788%	1.19E-08	8.50E-09	**4.249**
7	9/19/2012	6:30	7:32	1:02	**2.59E-08**	25.922%	4.38E-09	1.04E-09	**0.521**
8	9/19/2012	8:20	9:20	1:00	**3.87E-10**	0.387%			
9	3/6/2013	3:00	4:00	1:00	**2.73E-09**	2.730%	4.30E-10	6.48E-10	**0.324**
10	3/6/2013	4:00	5:00	1:00	**1.42E-10**	0.142%			
11	3/6/2013	5:00	6:00	1:00	**3.76E-09**	3.760%			
12	3/6/2013	6:00	7:00	1:00	**2.19E-10**	0.219%			
13	3/6/2013	7:00	8:00	1:00	**1.32E-09**	1.320%			
14	3/6/2013	8:00	9:00	1:00	**1.65E-10**	0.165%			
15	3/6/2013	9:00	10:00	1:00	**6.90E-10**	0.690%			
16	3/7/2013	3:00	4:00	1:00	**4.43E-10**	0.443%	1.42E-10	3.37E-11	**0.017**
17	3/7/2013	4:00	5:00	1:00	**6.39E-10**	0.639%			
18	3/7/2013	5:00	6:00	1:00	**4.88E-10**	0.488%			
19	3/7/2013	6:00	7:00	1:00	**3.93E-10**	0.393%			
20	3/7/2013	7:00	8:00	1:00	**4.58E-10**	0.458%			
21	3/7/2013	8:00	9:00	1:00	**1.93E-10**	0.193%			
22	3/7/2013	9:00	10:00	1:00	**3.63E-10**	0.363%			
23	3/8/2013	3:30	4:30	1:00	**1.73E-10**	0.173%	5.77E-11	4.11E-11	**0.021**
24	3/8/2013	4:30	5:30	1:00	**2.86E-10**	0.286%			
25	3/8/2013	5:30	6:30	1:00	**1.38E-10**	0.138%			
26	3/8/2013	6:30	7:30	1:00	**2.14E-10**	0.214%			
27	3/8/2013	7:30	8:30	1:00	**1.36E-10**	0.136%			
28	3/8/2013	8:30	9:30	1:00	**1.23E-10**	0.123%			

Assumption 1: **8** hrs of continuous exposure in the patio balcony area
Assumption 2: **5** days of exposure for **52** weeks per year
Assumption 3: **8760** hours in one year

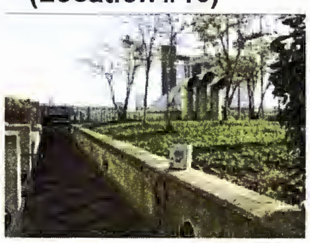
2012 St. Louis PETNET Air Sampling Locations

September 17^{th} – 19^{th} and December 18^{th} – 19^{th}

Monday September 17, 2012 (Location #7)

Monday September 17, 2012 (Locations #8 and #9)

Tuesday September 18, 2012 (Location #10)



Tuesday September 18, 2012 (Location #11)

Wednesday September 19, 2012 (Location #12)

Wednesday September 19, 2012 (Location #13)

2012 St. Louis PETNET Air Sampling Locations
September 17th – 19th and December 18th – 19th

Tuesday December 18, 2012 (Locations #14 - #18)



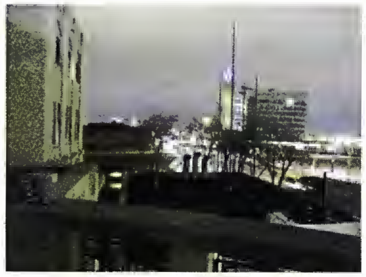
Wednesday December 19, 2012 (Locations #19 - #20)


Wednesday December 19, 2012 (Locations #21 - #24)


St. Louis PETNET Air Sampling Locations

March 6th – 8th, 2013

Wednesday March 6, 2013 (Locations #25 - #31)

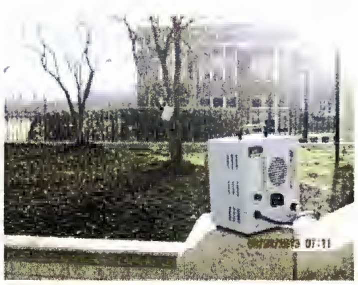



Thursday March 7, 2013 (Locations #32 - #38)



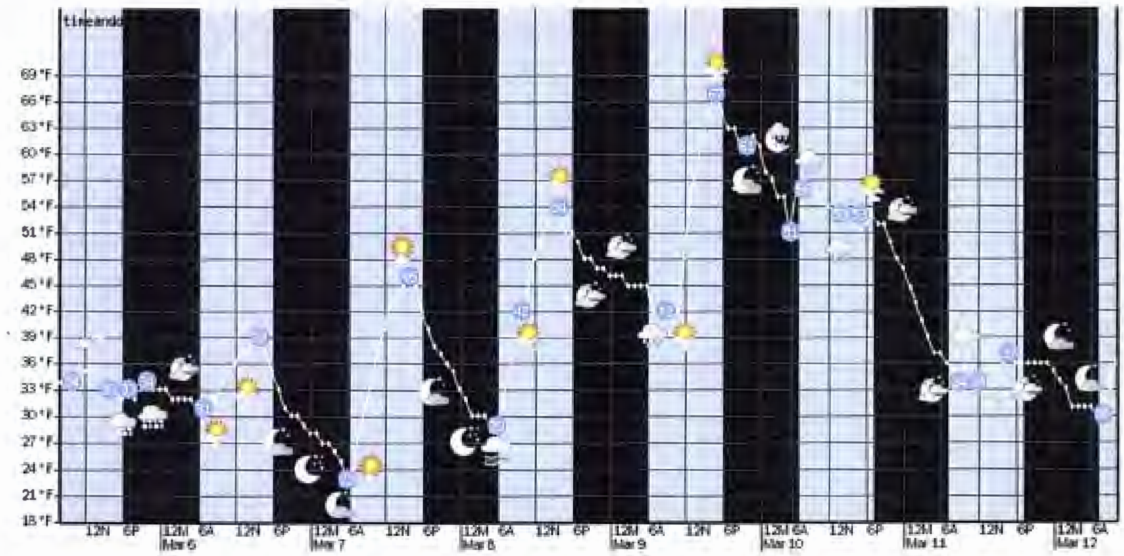
Friday March 8, 2013 (Locations #39 - #45)



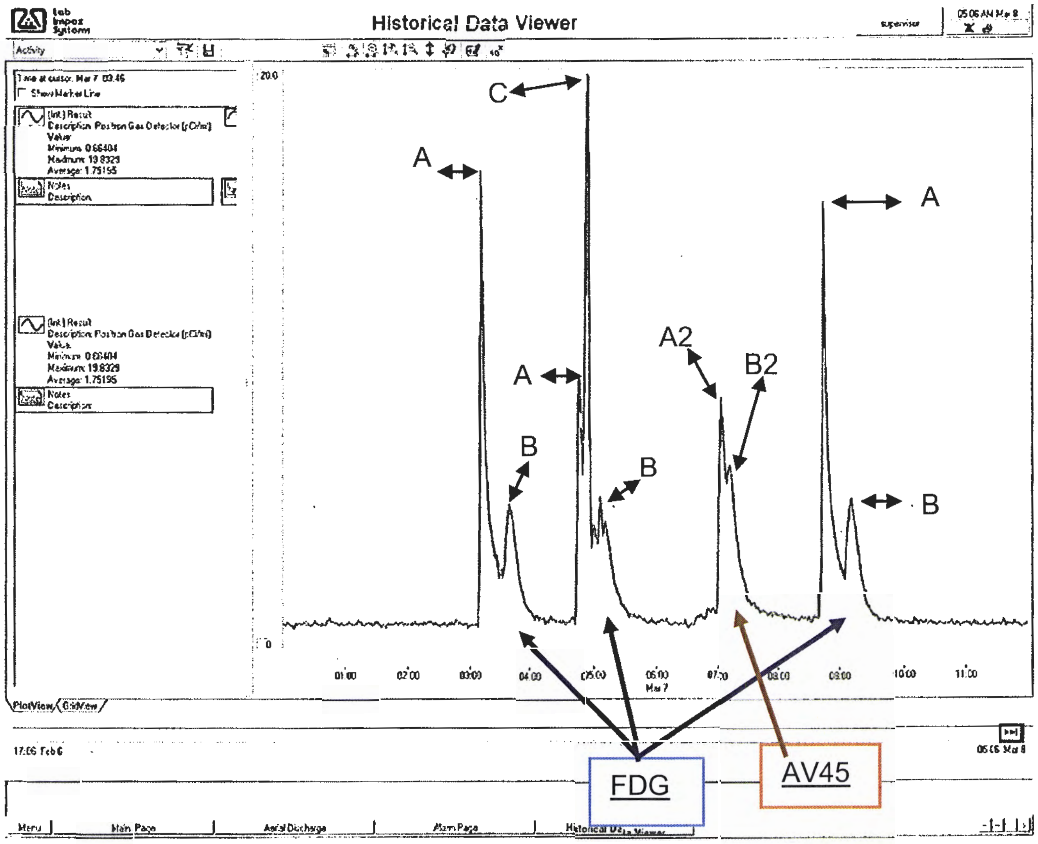



St. Louis PETNET Air Sampling Locations

March 6th – 8th, 2013



http://www.timeanddate.com/weather/usa/st-louis/historic



Peak Descriptions: FDG

A - Unload cyclotron & synthesis

B - Addition of mannose

C - Target rinse

AV45

A2 - Unload cyclotron & synthesis

B2 - Addition of precursor

Lab Impex Systems

Historical Data Viewer

supervisor

04:45 AM Mar 8

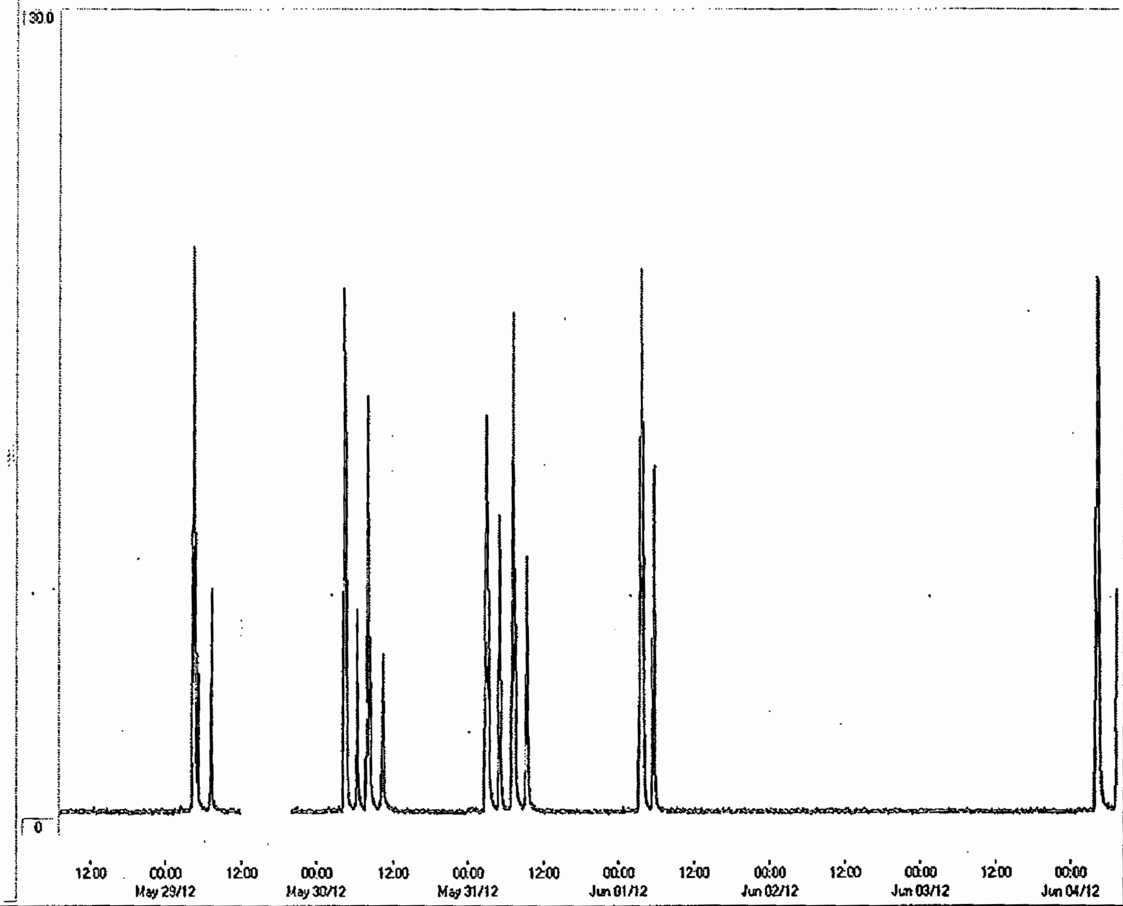
Activity | 1 Week | 10^x

Time at cursor:

Show Marker Line

(Int.) Result
Description: Positron Gas Detector (pCi/ml)
Value: 0.816759, 0.680219
Minimum: 0.577264
Maximum: 21.45
Average: 1.04412

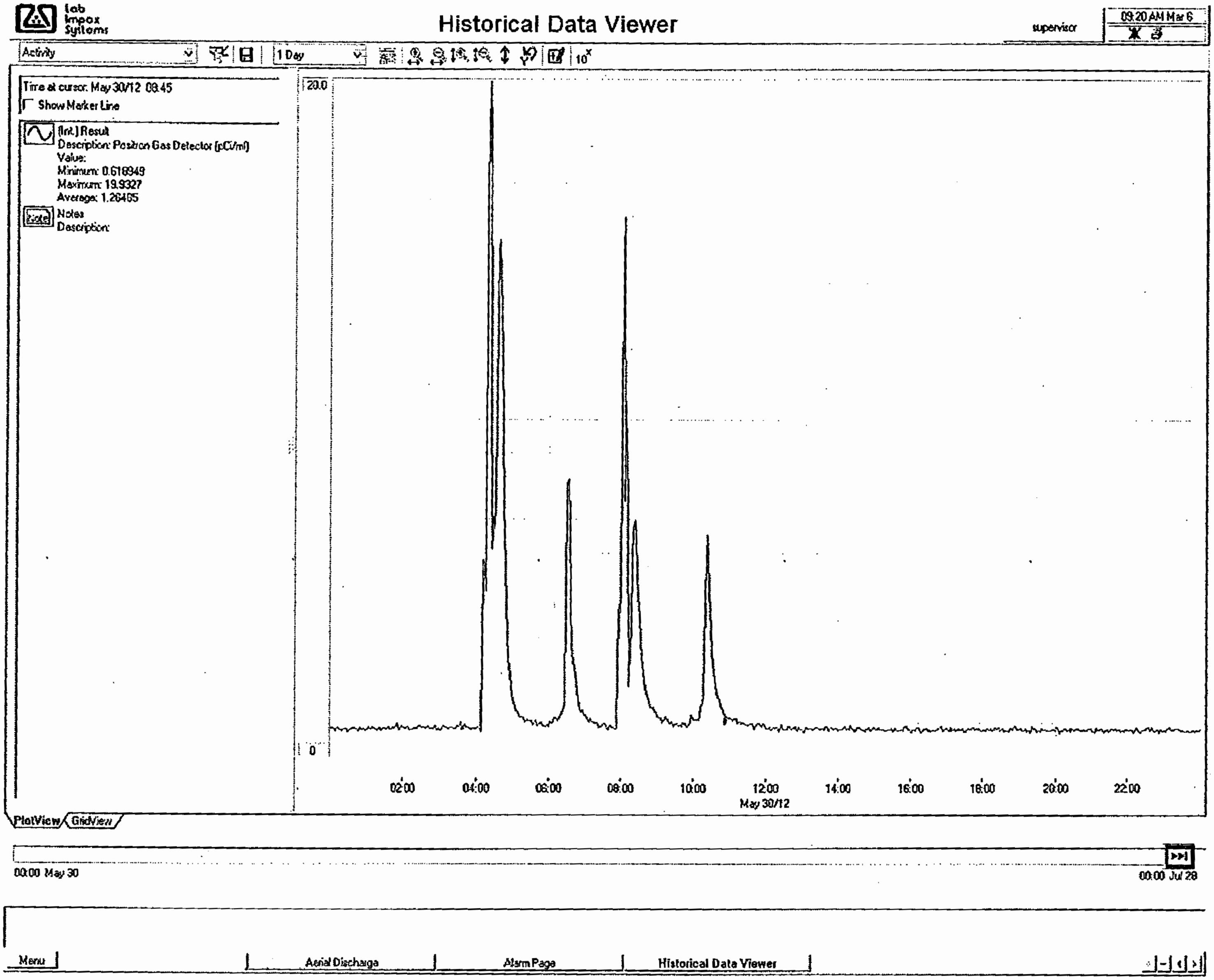
Notes
Description:



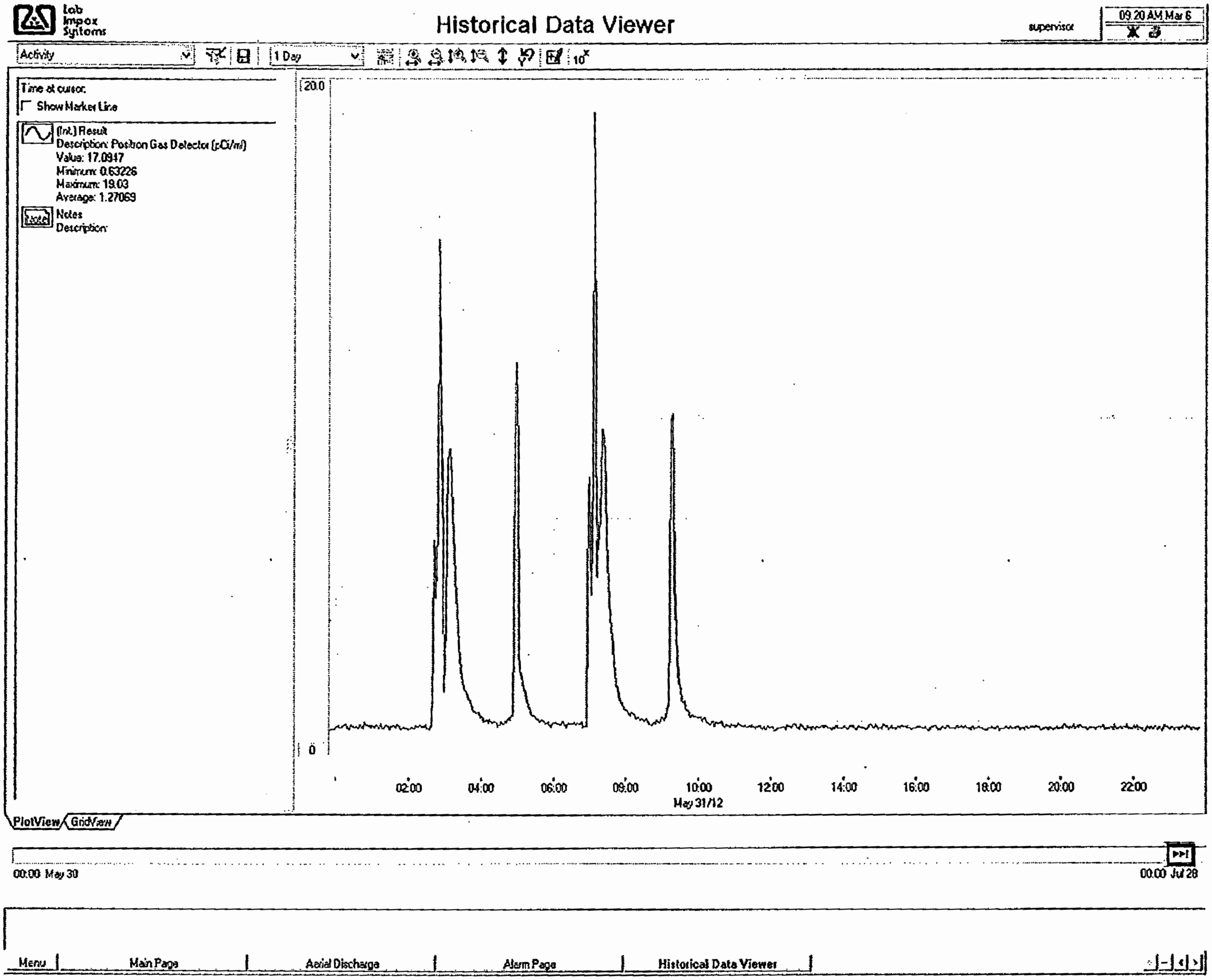
PlotView / GridView

Jan 20, 2012 — Mar 8, 2013

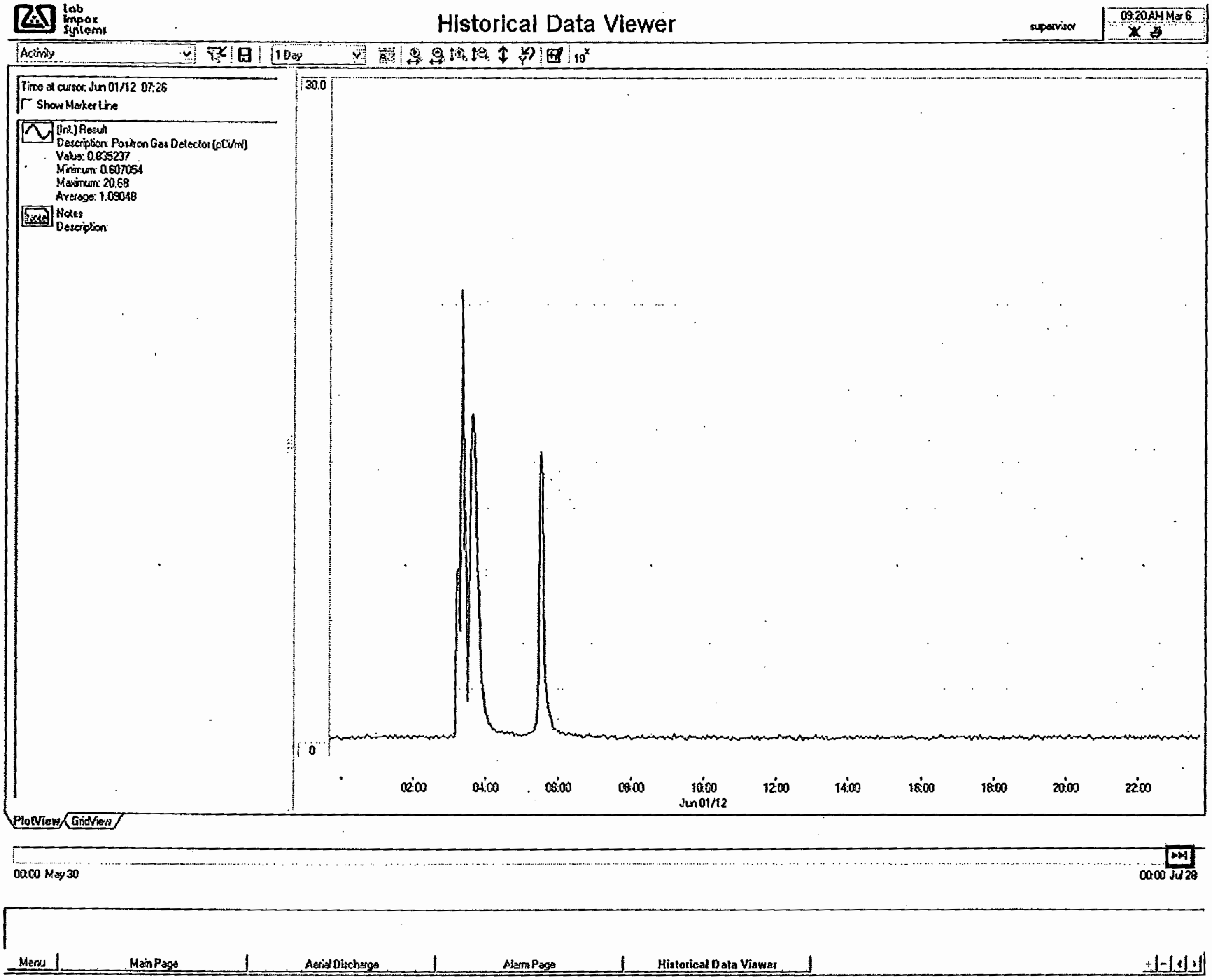
Menu | Main Page | Aerial Discharge | Alarm Page | **Historical Data Viewer**



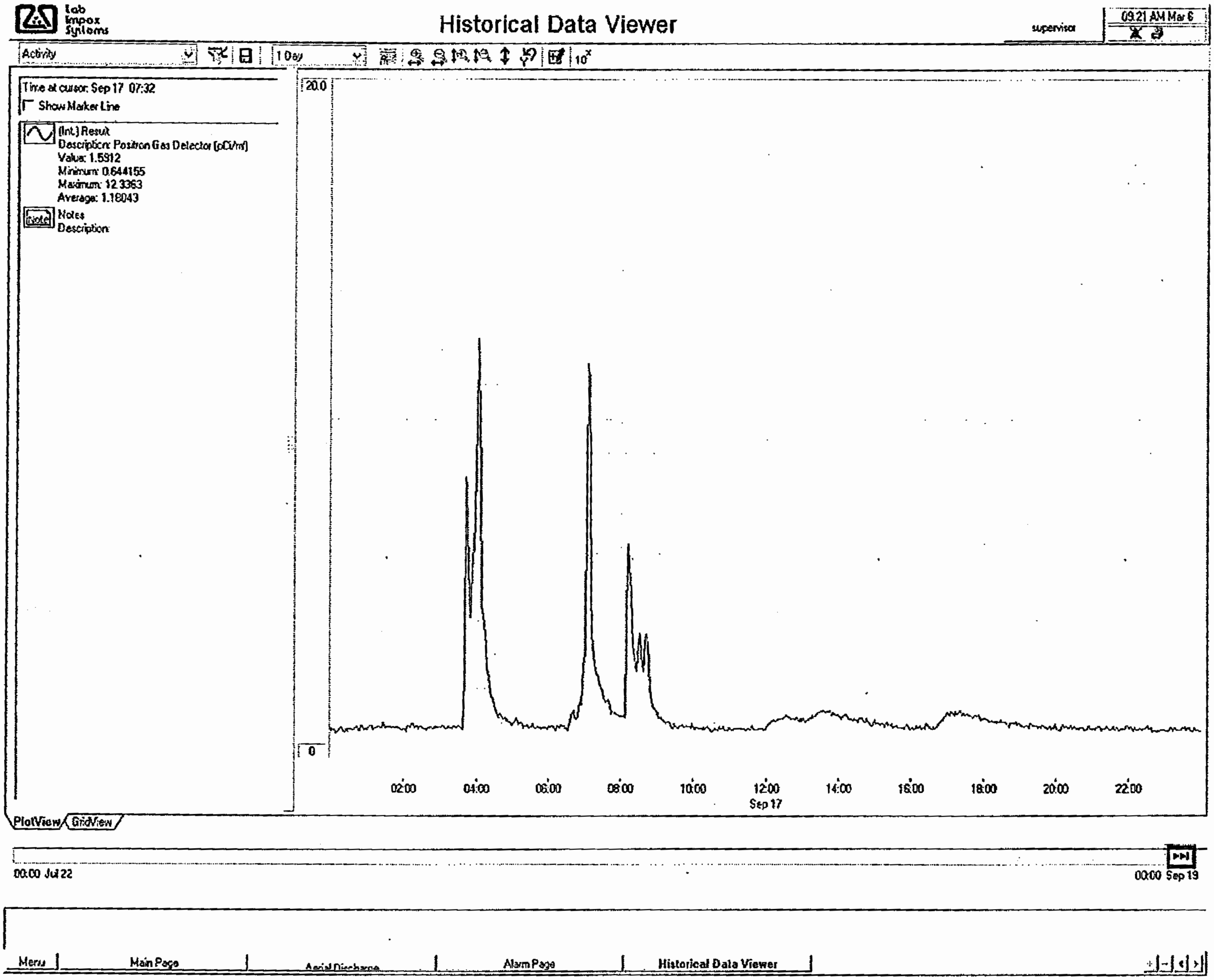
Runs	#1 (EOS: 5:00 am)	#2 (EOS: 7:18 am)	#3 (EOS: 8:44 am)	#4 (EOS: 11:03 am)
Max F- Produced (mCi)	6482	3907	2882	1522
Chemistry Yield	84%	36%	86%	14%
FDG (mCi)	3910	--	1798	--
AV-45 (mCi)	--	924	--	322



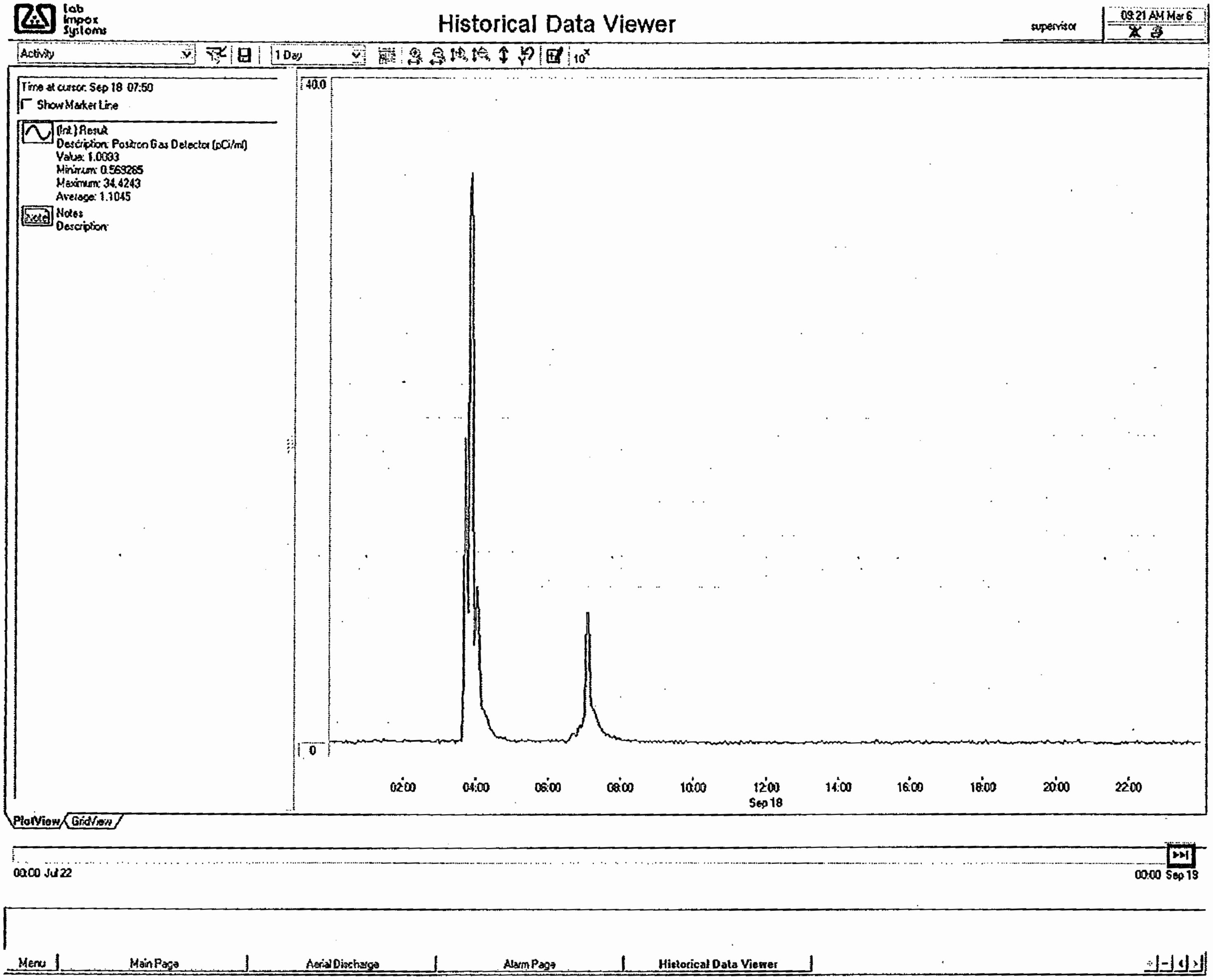
Runs	#1 (EOS: 3:30 am)	#2 (EOS: 5:50 am)	#3 (EOS: 7:45 am)	#4 (EOS: 10:08 am)
Max F- Produced (mCi)	6656	3897	5691	3907
Chemistry Yield	89%	37%	89%	36%
FDG (mCi)	4240	--	3620	--
AV-45 (mCi)	--	841	--	829



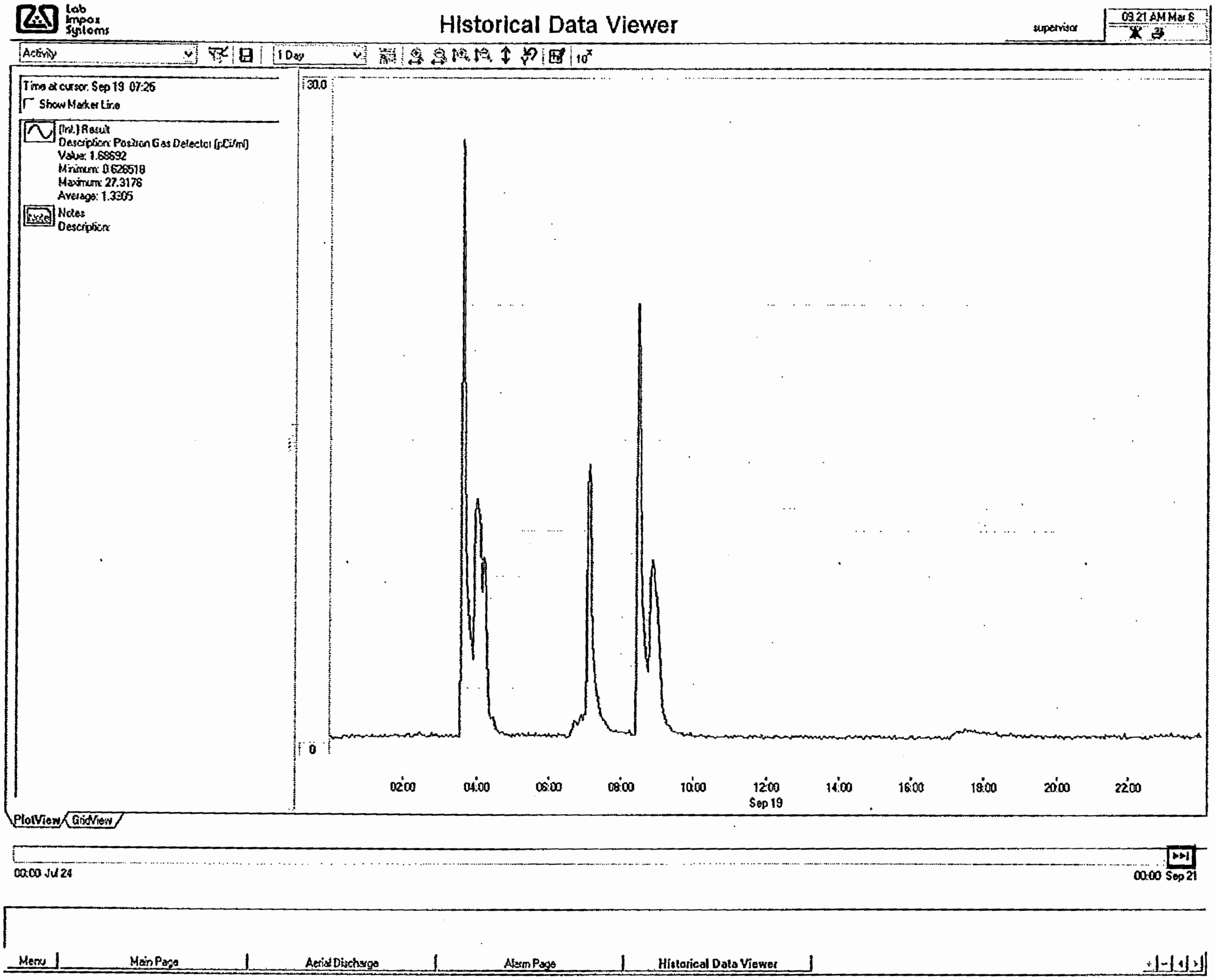
Runs	#1 (EOS: 4:01 am)	#2 (EOS: 6:21 am)
Max F- Produced (mCi)	6328	3825
Chemistry Yield	89%	37%
FDG (mCi)	4020	--
AV-45 (mCi)	--	831



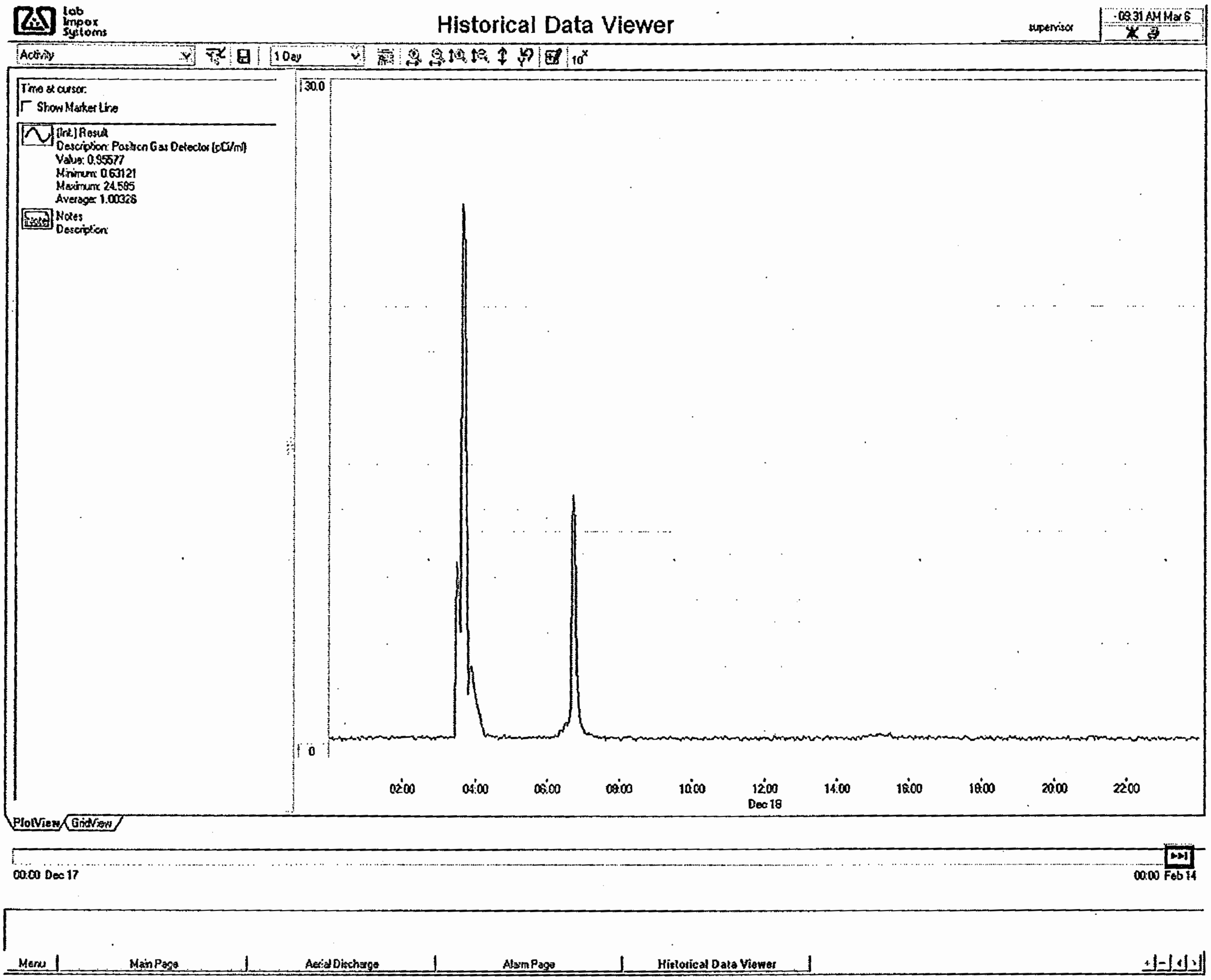
Runs	#1 (EOS: 4:30 am)	#2 (EOS: 7:56 am)	#3 (EOS: 8:57 am)
Max F- Produced (mCi)	7169	4338	2289
Chemistry Yield	87%	49%	88%
FDG (mCi)	4400	--	1452
AV-45 (mCi)	--	1219	



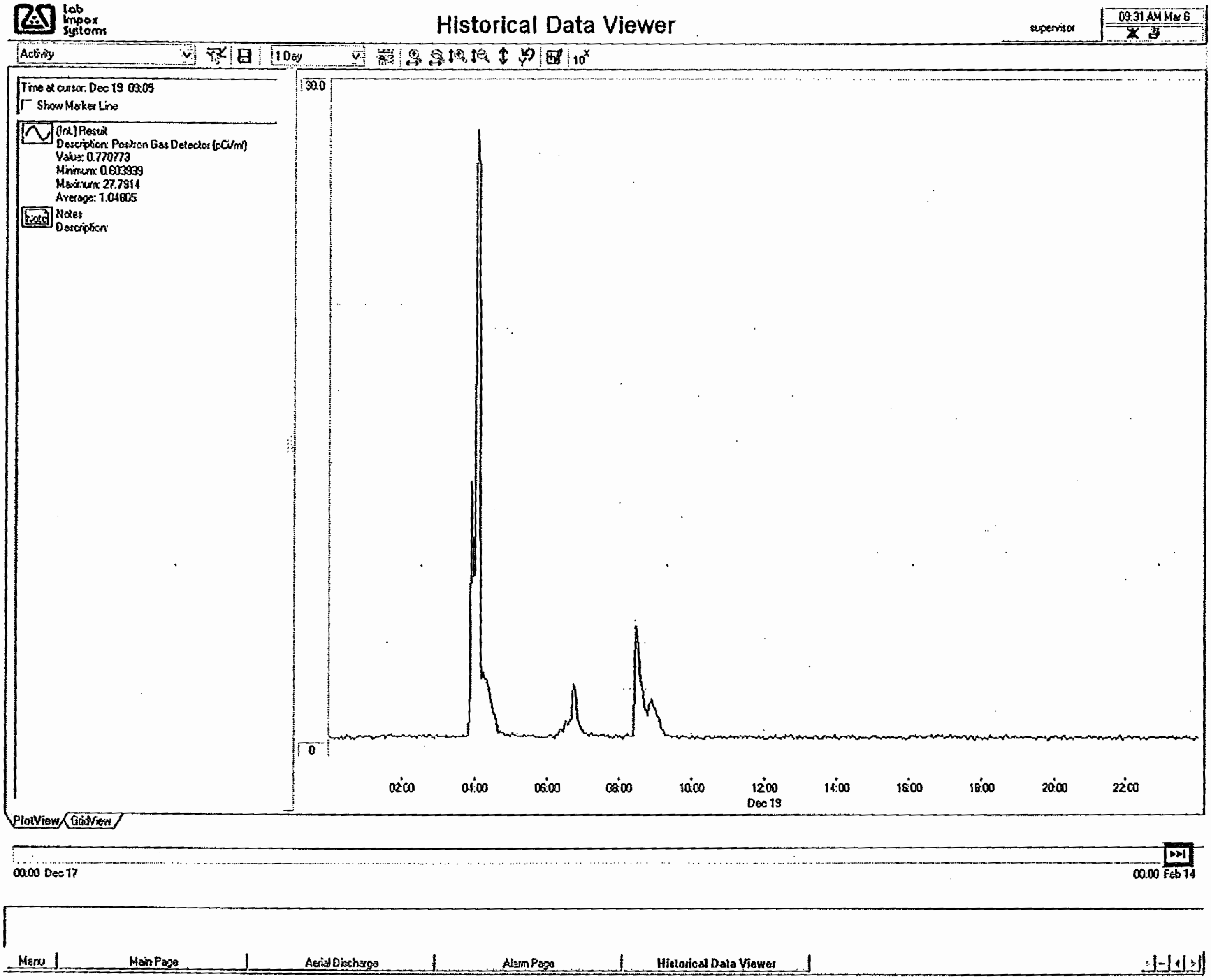
Runs	#1 (EOS: 4:30 am)	#2 (EOS: 7:57 am)
Max F- Produced (mCi)	6646	3924
Chemistry Yield	91%	46%
FDG (mCi)	4340	--
AV-45 (mCi)	--	1034



Runs	#1 (EOS: 4:25 am)	#2 (EOS: 8:01 am)	#2 (EOS: 9:15 am)
Max F- Produced (mCi)	6685	3975	4709
Chemistry Yield	89%	48%	89%
FDG (mCi)	4228	--	3000
AV-45 (mCi)	--	1065	--



Runs	#1 (EOS: 4:20 am)	#2 (EOS: 7:28 am)
Max F- Produced (mCi)	6747	4122
Chemistry Yield	69%	34%
FDG (mCi)	3262	--
AV-45 (mCi)	--	916



Runs	#1 (EOS: 4:45 am)	#2 (EOS: 7:28 am)	#3 (EOS: 9:15 am)
Max F- Produced (mCi)	7226	4005	2917
Chemistry Yield	82%	39%	80%
FDG (mCi)	4200	--	1635
AV-45 (mCi)	--	1045	--

Lab Impex Systems

Historical Data Viewer

supervisor

08:31 AM Mar 8

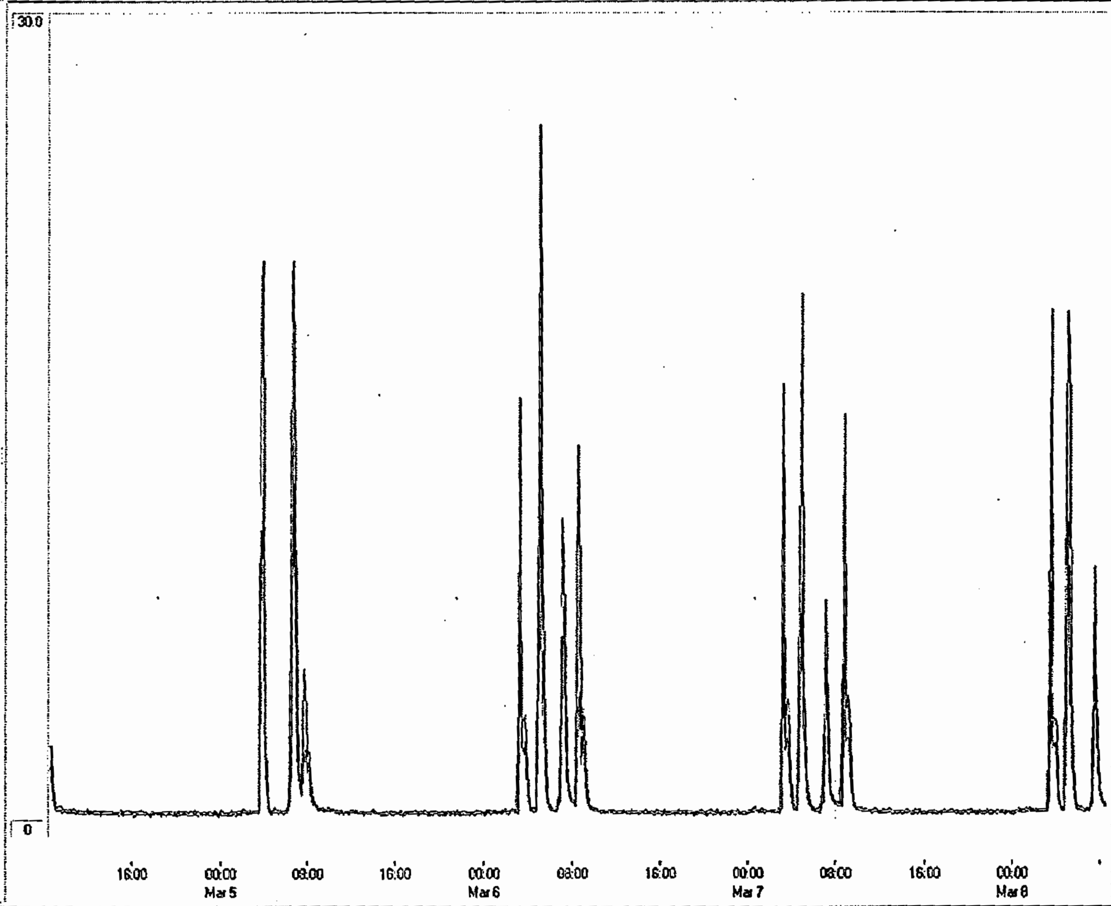
Activity

Time at cursor: Mar 5 15:15

Show Marker Line

(Int.) Result
Description: Positron Gas Detector (pCi/ml)
Value: 0.76356, 0.846928
Minimum: 0.610518
Maximum: 25.9009
Average: 1.27094

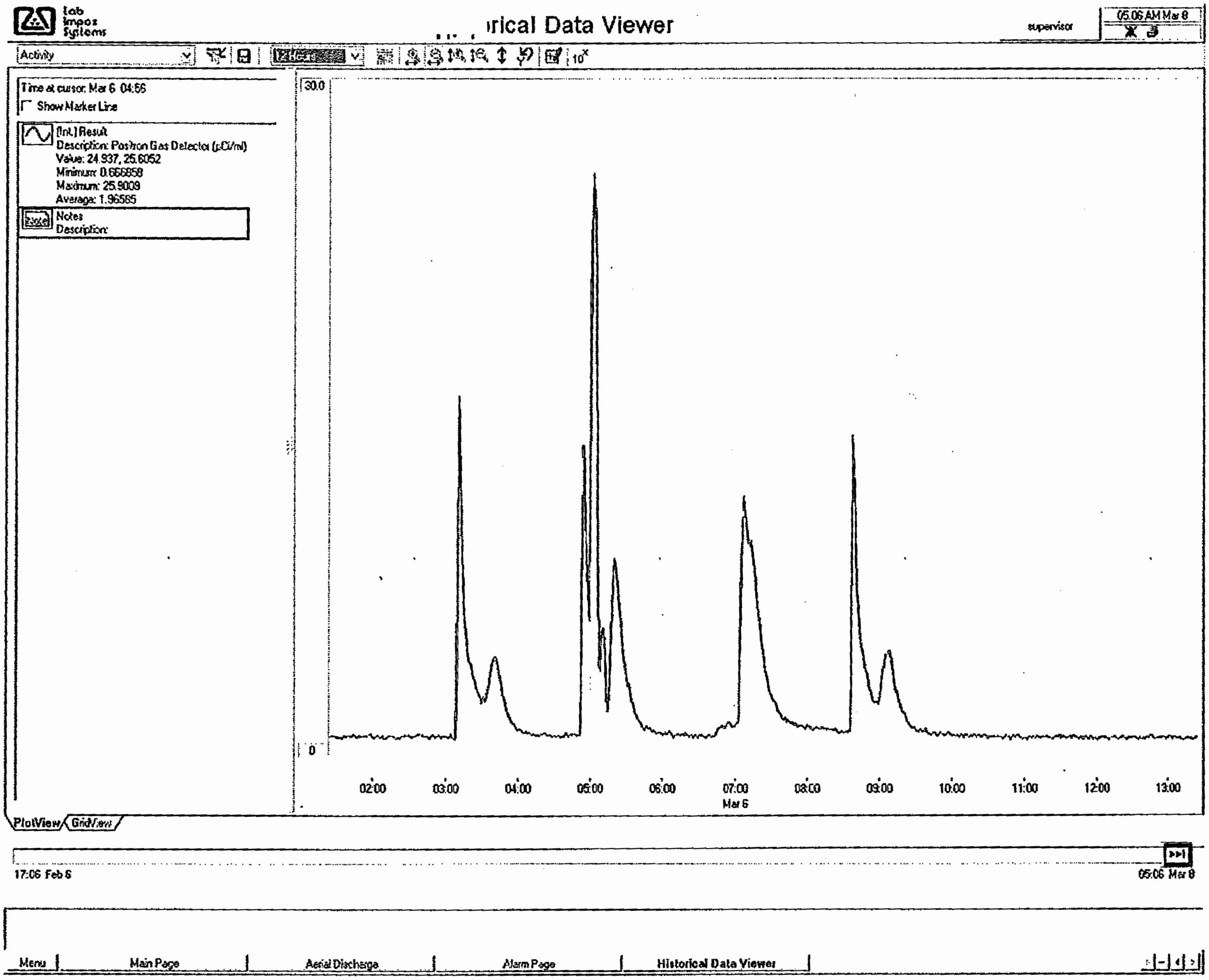
Notes
Description:



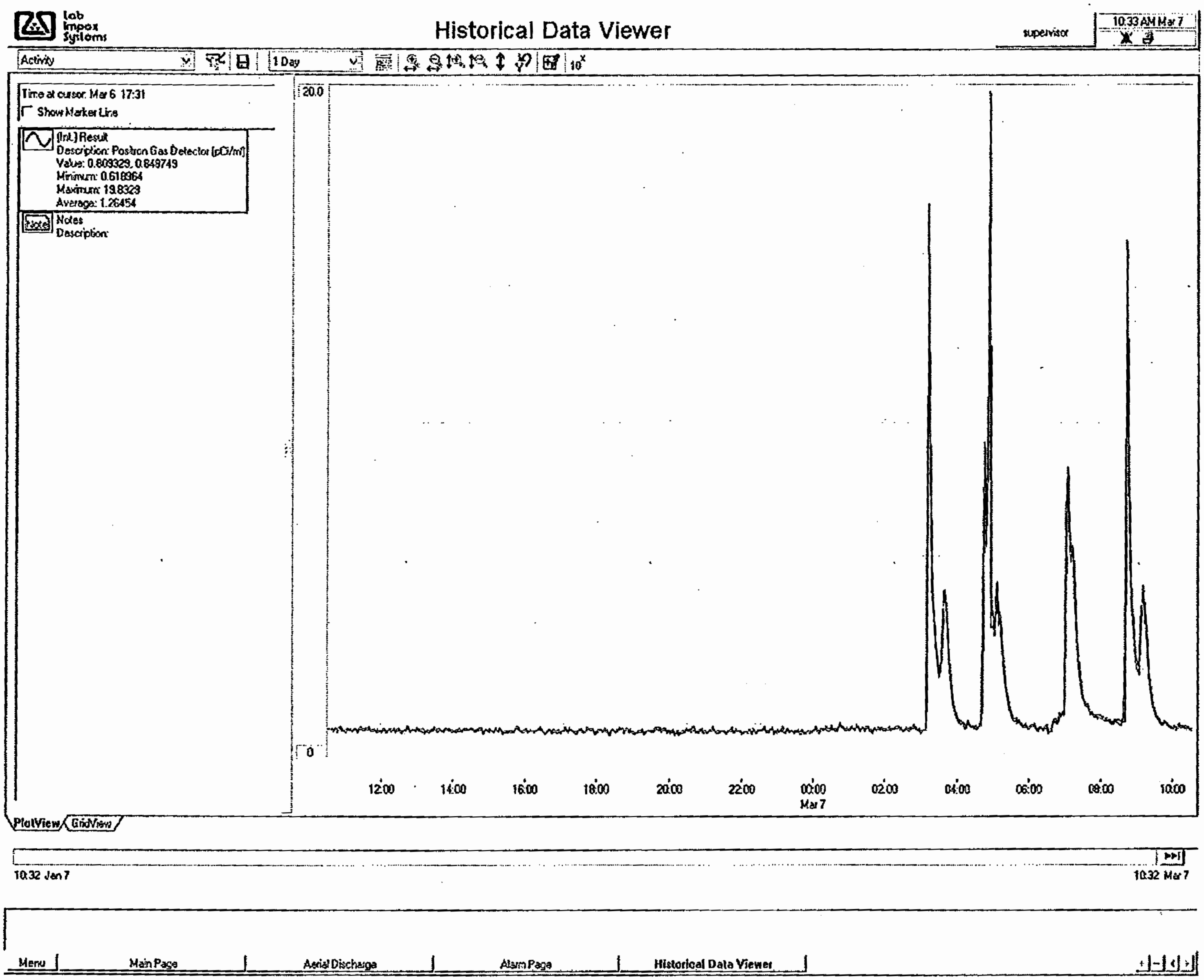
PlotView GridView

Jul 15 Mar 8

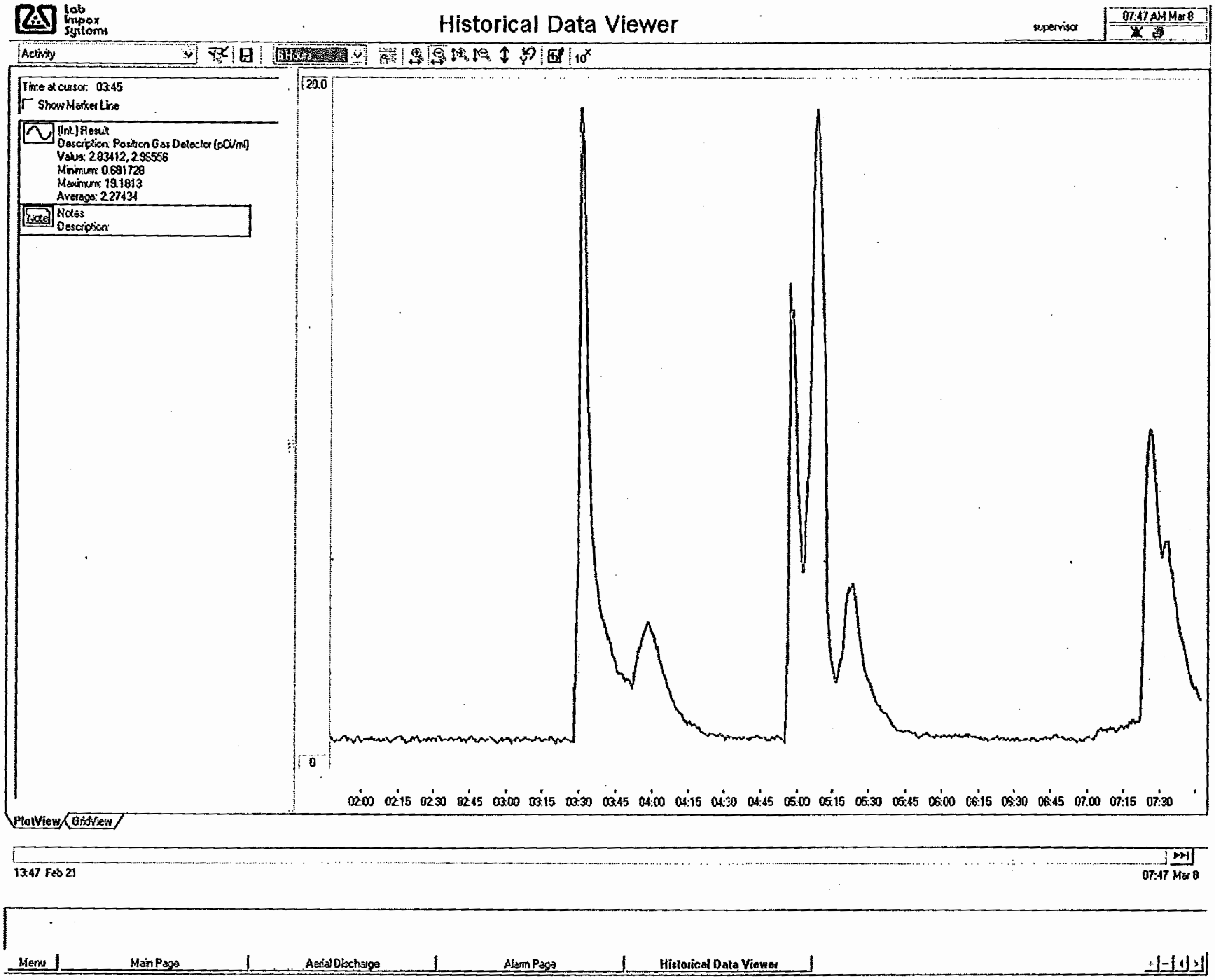
Menu | Main Page | Aerial Discharge | Alarm Page | Historical Data Viewer



Runs	#1 (EOS: 4:00 am)	#2 (EOS: 5:42 am)	#3 (EOS: 7:58 am)	#4 (EOS: 9:30 am)
Max F- Produced (mCi)	7205	5100	3960	5037
Chemistry Yield	87%	87%	37%	86%
FDG (mCi)	4340	3200	--	2960
AV-45 (mCi)	--	--	824	--



Runs	#1 (EOS: 4:00 am)	#2 (EOS: 5:39 am)	#3 (EOS: 7:47 am)	#4 (EOS: 9:30 am)
Max F- Produced (mCi)	7113	4196	3520	5302
Chemistry Yield	87%	91%	41%	89%
FDG (mCi)	4370	2710	--	3390
AV-45 (mCi)	--	--	965	--



Runs	#1 (EOS: 4:21 am)	#2 (EOS: 5:45 am)	#3 (EOS: 8:16 am)
Max F- Produced (mCi)	7241	4123	3720
Chemistry Yield	89%	92%	44%
FDG (mCi)	4180	2460	--
AV-45 (mCi)	--	--	929

ATTACHMENT C
TEST SUPPORT DOCUMENTS

Measurement of Collection Efficiency in Activated Charcoal Cartridges for Air Samples of Volatile ^{18}F Releases from PET Radiopharmaceutical Manufacturing. D.J. Krueger, CHP, PETNET Solutions, Inc.

Abstract
Manufacture of ^{18}F radiopharmaceuticals often results in volatile compounds being generated. Typically, very expensive stack monitoring systems are used to monitor these releases. This paper discusses the use of activated charcoal cartridges impregnated with TEDA (triethylenediamine) and two separate pump systems that can be used for duct or ambient air sampling. The key to utilizing such a system is to determine the collection efficiency for the ^{18}F compounds on these cartridges. To determine the collection efficiency, $H^{18}F$ gas was generated and passed through a series of cartridges. The fraction collected on the first and subsequent cartridges is analyzed to assess the percentage collected on each cartridge. [Slides summarizing this data were presented at the 2013 Health Physics Society Mid-year Meeting in Scottsdale, AZ]

Introduction
The use of TEDA-impregnated activated carbon cartridges has been the standard air sampling technique for monitoring the volatile uses of ^{125}I and ^{131}I sodium iodide solutions for decades. It involves pulling air to be sampled through a cartridge holder containing one TEDA cartridge. Typical room air or duct air is sampled at a nominal 10 liter/minute (L/min). Environmental sampling often involves flow rates of 4-10 cubic feet/minute (110-280 L/min).

The chemical synthesis of ^{18}F-labeled compounds for positron-emission tomography (PET) scans results in releases of volatile $H^{18}F$. Typically, commercial PET drug production involves curies of ^{18}F produced in a cyclotron and processed into PET drug in an automated chemistry module. Gaseous releases are seen when the target material (^{18}O-enriched water) is pushed out of the cyclotron target to a receiving container and during certain steps in the synthesis process. A number of commercially available "PET effluent monitors" are available to monitor the releases; such monitors can cost up to $100,000. ^{18}F drug synthesis typically is performed in shielded, negative-pressure enclosures, such as hot cells. The engineering controls of negative pressure have prevented releases into production suites and room air contamination is virtually zero in such facilities.

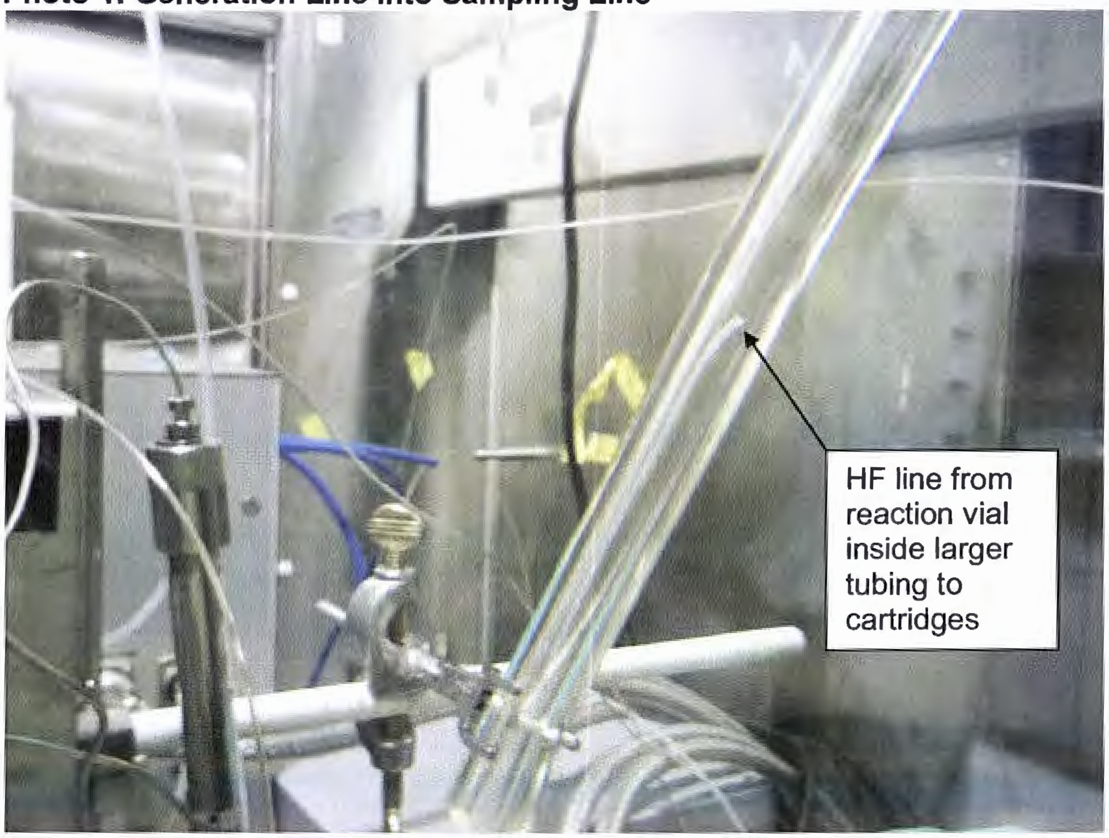
There are circumstances where room air or environmental air concentrations need to be measured or verified. The commercial stack monitors do not generally have a method of measuring ambient air. This paper discusses the use of the radioiodine sampling system for air monitoring of PET drug manufacturing effluents.

Two sets of experiments using TEDA carbon cartridges were conducted under a variety of conditions. One set was performed using a low volume flow rate (10 L/min). Multiple cartridges were set up in series to gauge the breakthrough from one filter and estimate the collection efficiency of a single cartridge that would be used for actual air sampling.

Generation of HF Gas

The production of ^{18}F involves the irradiation of ^{18}O-enriched water to create $^{18}F^-$ fluoride ion in water. In the collection efficiency experiments, a sample of the fluoride solution was transferred to a hot cell and then to an automated chemistry box. The fluoride solution was passed through a cation exchange (QMA) cartridge where the F^- was trapped. It was washed off the QMA with acetonitrile and Krypofix 222 (4,7,13,16,21,24-Hexaoxa-1,10-diazabicyclo [8.8.8] hexacosane) and moved to a reaction vial. The solution was dried by heating leaving the fluorine ion in the reaction vial. After the fluoride was dry, 0.5 mL of 3 N HCl was added. This creates HF, which is volatile and extremely reactive. Immediately before the HF was generated, the sampling pump was turned on and the valve from the closed reaction vial was opened. Helium push gas was used to drive the HF through small 1/8th inch outer diameter (OD) tubing. The small tubing was placed loosely into a 3/8th inch inner diameter (ID) tubing of the sampling system. This allowed the HF to flow into the larger tubing where ambient air was also drawn in, see Photo 1. The tubing was connected to a series of aluminum cartridge holders each with a TEDA-impregnated, activated-carbon cartridge.

Photo 1: Generation Line into Sampling Line



The generation of HF was performed at several temperatures between 60-80°C and for several durations.

General Concepts of Measuring Collection Efficiency

As HF gas is so reactive, it is extremely difficult to measure the activity presented to the collection media and measure the collected fraction directly. In the first set of experiments (low-volume runs) discussed below, only a relative measure of the starting activity was made and no attempt to measure what the fraction of the activity that was released.

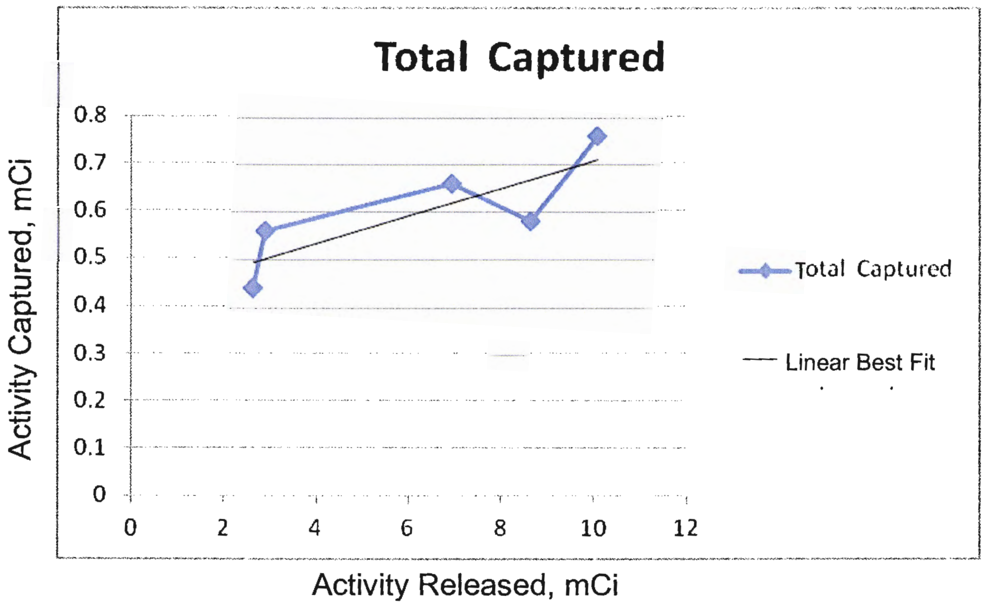
In the second set of experiments (high-volume, 1-hour runs), the activity at the beginning and end of the generation process was measured by taking the reaction vial to an active nuclear pharmacy's dose calibrator. Even this step, which supplies the activity of the generated HF gas, does not help determine the activity that was presented to the cartridges. Table 1 shows the starting and ending activity and the activity trapped on cartridges:

Table 1: Activity Released and Captured

Run	Initial Activity	Ending Activity	Activity Released	Total Captured
6	4.02	1.40	2.62	0.44
3	4.22	1.34	2.88	0.56
5	10.42	3.50	6.92	0.66
4	13.10	4.47	8.63	0.58
2	15.17	5.11	10.06	0.76

Graph 1 shows that the captured activity is somewhat related to activity released

Graph 1: Activity Captured vs. Activity Released



Collection Efficiency (CE) is typically defined as:

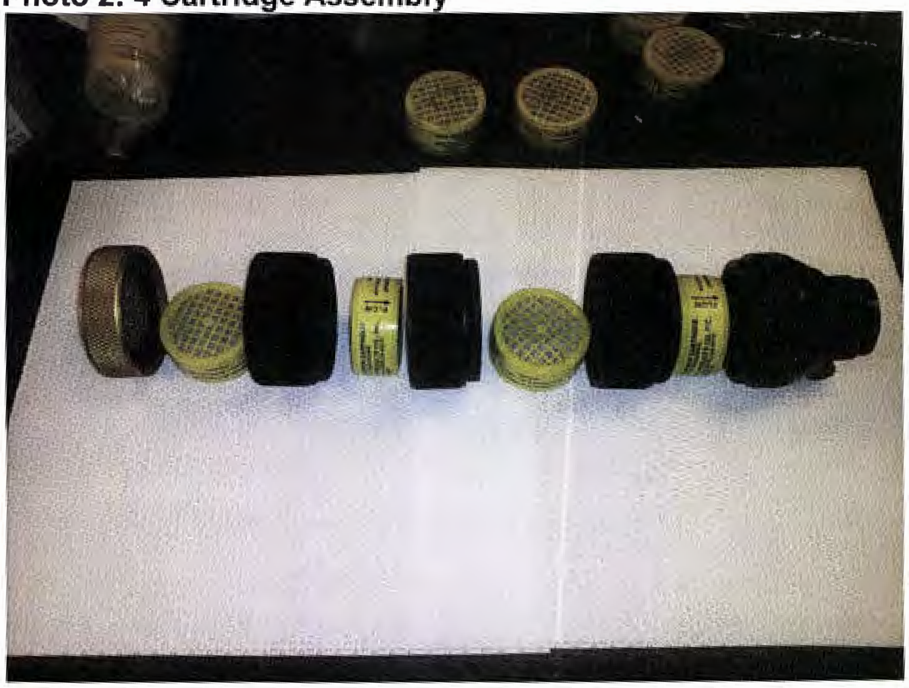
Activity collected on collection media/Activity entering collection media = CE   Eq. 1

It may appear that the data in Table 1 could be used to calculate the collection efficiency, but that conclusion is false. HF is so reactive it sticks to any surface it touches. As can be seen in Table 1, a significant portion of the starting activity remains on the reaction vial and is not released. In addition to losses in the reaction vial, significant activity sticks to the tubing, the cartridge holders and anything that comes in contact with the gas. Surveys of the tubing and holders showed them to be very contaminated, reading several mR/hr at a foot after a collection experiment. This complicates the assessment of the collection efficiency with such a reactive gas.

Instead of a mass balance assessment to calculate the collection efficiency as in Eq. 1, a simple assumption has to be made: that the activity on the first filter, relative to the total captured on all filters is a reasonable assessment of the collection efficiency. Therefore putting cartridges in series should allow calculation of a collection efficiency that is fairly accurate.

Photo 2 shows a four cartridge series in disassembled form:

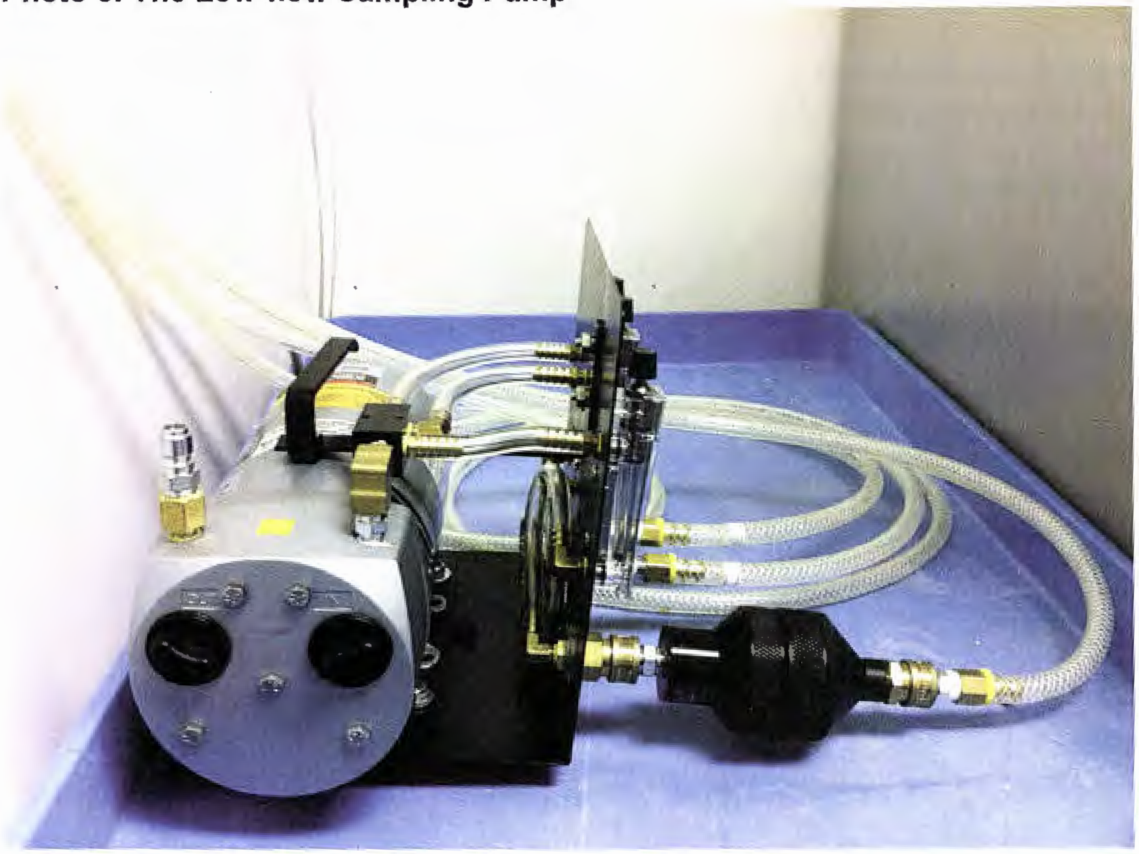
Photo 2: 4 Cartridge Assembly



The activated cartridges used were from Hi-Q Environment Products Company in San Diego. Model TC-12, TEDA-impregnated activated carbon 8x16 mesh; 2.5"x1" plastic.

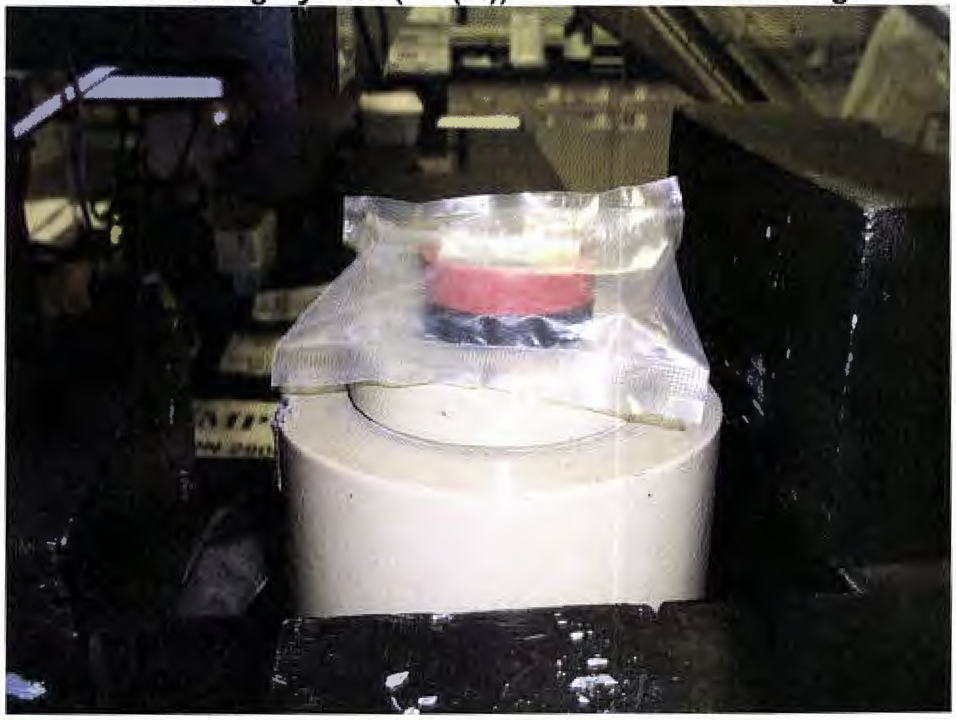
Experiment 1: Low Volume Collection Efficiency
For the low volume (10 L/minute) experiments, four TEDA cartridges were connected in series, so that whatever passed through the first filter was trapped on subsequent cartridges.

Photo 3: The Low-flow Sampling Pump



After the HF gas was generated and pulled through the cartridges, the sample train was disassembled and the cartridges were transferred to sealed plastic bags and labeled. The samples and an NIST-traceable standard (^{137}Cs) were counted using a sodium iodide well counter with a single channel analyzer (Photo 3). Both the mid-times for the generation and for the counting were used to calculate the activities on the samples.

Photo 4: Counting System (NaI(Tl)) with Standard Cartridge on Top of Well



In this set of experiments, a glass fiber filter was used as is standard for cartridge air sampling. As HF reacts with glass it is collected effectively on the glass fiber filter. The activity collected on such filters is typically interpreted as particulate activity, as opposed to gaseous activity that is collected on activated carbon. Due to the nature of the gas generation process, no particulates were generated. Therefore, the activity measured on the glass fiber filter and first carbon cartridge (referred to as "1", below) were combined and compared to the total activity on the first, second, third and fourth cartridges.

$$CE = 1 / (1+2+3+4) \quad \text{Eq. 2}$$

During these low-flow experiments, the actual activity of gas produced was not able to be determined. It was known from surveys that not all of the activity that dried in the reaction vial was released as a gas since the reaction vial had significant radiation levels after the completion of the generation/collection process. Instead, comparison of the activity on the first cartridge to the subsequent cartridges was used to determine collection efficiency.

Details of the four 10 L/minute runs are provided in Table 2 below.

Table 2: Low Volume Experiment Results

Run	Initial Activity (mCi)	Duration of Release and Collection (min)	Activity Trapped on Cartridge μCi 1	2	3	4	Collection Eff. of 1st Cartridge (fraction)
1	104.8	30	3690.6	0.06247	0.04060	0.01562	0.99997
2	1.00	30	642.24	0.01022	0.00307	0.00307	0.99997
3	1.08	30	342.42	0.00866	0.00144	0.00866	0.99995
4	1.09	10	298.84	0.00276	0.00737	0.00368	0.99995
						Average	**0.99996**
						2 sigma	**2.3E-05**

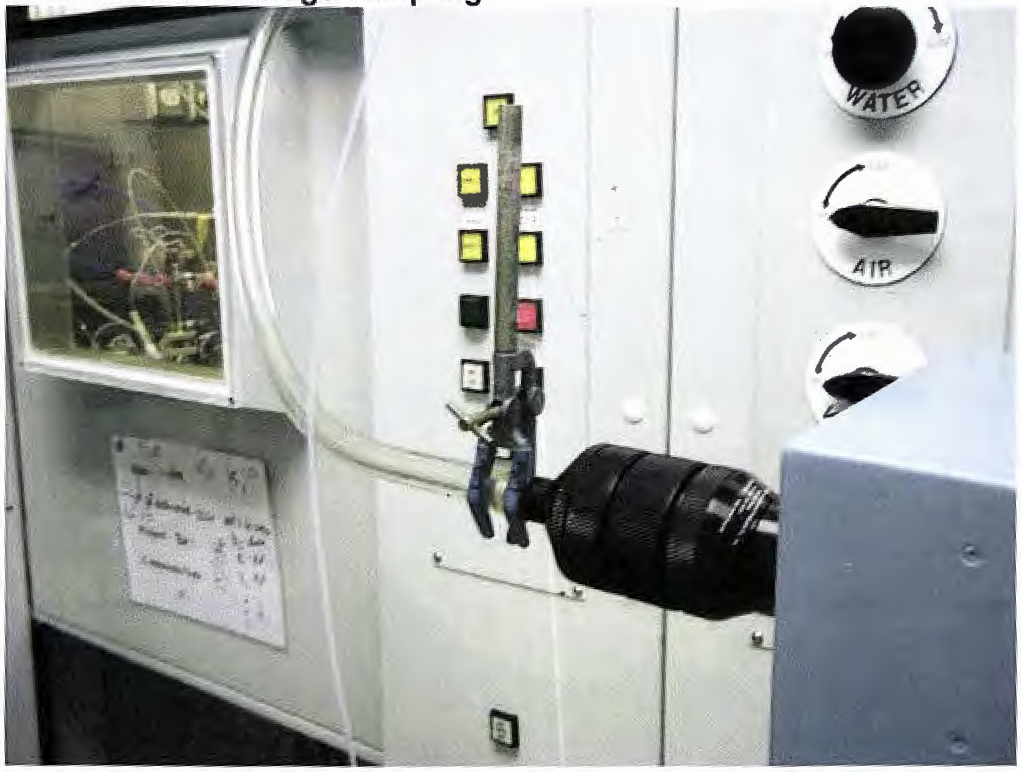
The generation of the HF gas mimics the actual process in ^{18}F radiopharmaceutical manufacturing. At 10L/min, the collection efficiency on the first carbon cartridge was demonstrated to be 99.99% of collected gas.

Experiment 2: High Volume Sampling (8 cfm) for 1 Hour Collection Times

The purpose of the second set of experiments was to characterize the high-volume sampling for a 1-hour sampling period. One hour represents the time during which volatiles are generated in an automated synthesis module for ^{18}F radiopharmaceuticals: from delivery of the target water to a collection vial and subsequent push to the automated chemistry module that synthesizes the ^{18}F drugs. The step in this process that has been shown to create the most volatile release is the drying and reconstitution of the fluorine ions.

In this final set of experiments, only two cartridges in series were used (Photo 5). This resulted in less restriction on flow and allowed an 8 cfm maximum flow rate. The second cartridge was used to show the percentage of breakthrough and the combined trapped activity was compared to the activity on the first cartridge to calculate collection efficiency.

Photo 5: Two-cartridge Sampling



The results for the third experiment are shown in Table 4:

Table 4: High Volume with 60 Minute Sample Time Experiment

			Activity Trapped on Carbon Cartridge (µCi)			Collection Eff of 1st Cartridge (fraction)
Run	Net Activity (mCi)	Time of Release and Collection (min)	1	2	Total	
2	10.06	60	709.996	51.703	761.699	0.932121
3	2.62	60	432.765	3.788	436.553	0.991323
4	8.63	60	557.145	21.827	578.971	0.962301
5	6.92	60	628.917	33.556	662.473	0.949347
6	2.88	45	529.705	25.533	555.238	0.954014
					Average	**0.957821**
					2 Sigma	**0.043466**

Therefore for a one-hour sample in the 8 cfm range the collection efficiency is 95.7%±4.3. Based on this data, a conservative collection efficiency for actual single cartridge sampling would be 91%.

Conclusions
The experiments show that the collection of HF gas on TEDA-impregnated carbon cartridges can be for determining air concentration is feasible. With low flow rates, the collection efficiency was very consistent and reproducible. The fact that the activity collected on the first cartridge is 5 orders of magnitude greater than that collected on subsequent cartridges. At 10 L/min the CE is 99.99%.

Higher sampling flow rates results in the contaminant being pulled through the carbon at a rate that is less than optimal. Regardless, the high flow rate still resulted in a CE greater than 90%.

Date: January 14, 2013
By: David J. Krueger, CHP

PETNET PHARMACEUTICALS, INC.

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PROPRIETARY

Determination of Air Effluent Release Fraction from [^{18}F][FDG] Manufacturing

Roger Moroney, CHP
CTI Molecular Imaging
PETNET Pharmaceuticals
Knoxville, TN

May 26, 2004

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Testing was conducted to determine what fraction of activity was released to the air exhaust system during manufacturing of ^{18}F labeled Fluorodeoxyglucose. Release fractions are dependent on the type of chemistry module used. For this test, the CPCU chemistry module, manufactured by CTI, Inc., was used.

For this test, all filters were removed from the KEP3S filter housing. No other filters were present in the system except for the small carbon trays on the CPCU itself. It has been previously shown that these are of negligible value in reducing effluents of this magnitude and their effectiveness is further reduced if not properly maintained. The effluent monitor is an Eberline FHT3511. These units are calibrated at the factory using a small solid source containing ^{68}Ge. Calibration checks are completed upon installation of the unit and on a quarterly basis thereafter. The effluent monitor used in this test was operating within specifications.

These tests were conducted over the period of July 8 to 11, 2003 and encompass four production days. Due to the high release activities observed, further testing without filters was discontinued. Table 1 shows the production data for these four days for each run. Each run activity is measured shortly after the end of the cyclotron run by use of a dose calibrator. After completion of the FDG synthesis, the activity is measured in a dose calibrator. Yields are decay corrected based on the time at end of bombardment (EOB) and end of synthesis (EOS). These dose calibrators are checked on a daily basis for constancy.

The quantity of activity that could be released is related to the process yield and, in the case of sub-standard yields, the specific cause of the low yield. In some situations it is possible to have an extremely poor yield (<30%) and not see any release as the radioactive material is retained in the reaction vessel.

Table 1

Date	Run #	F- (mCi)	FDG @ EOS (mCi)	Yield (%)
7/8/2003	1	6763	3000	61
	2	4433	2093	65
	3	2414	938	60
	4	1798	845	68
7/9/2003	1	7378	2918	55
	2	4205	2590	56
7/10/2003	1	9968	3663	63
	2	5655	2280	58
	3	6627	2496	55
	4	1405	565	58
7/11/2003	1	9692	3520	53
	2	5154	2234	63
	3	7780	2214	41

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The daily total activity produced is shown in Table 2 along with the total activity released for the day.

Table 2

Date	F- Total (mCi)	Effluent Release (mCi)	Fraction of F-
7/8/2003	15,408	246.9	0.01602
7/9/2003	18,274	338.5	0.01852
7/10/2003	23,655	467	0.01974
7/11/2003	22,626	360	0.01591

The average unfiltered release fraction for this experiment was 0.0176 of the total activity made for the day. The standard deviation of this average is 0.0019.

The process yields for these four days are on the low side. Typically yields are in the upper 60% range. As such, these numbers represent releases that are higher, on average, then what would be expected. Possible sources of error in this experiment are in measurement of activity at EOB or EOS, and determination of air flow in the exhaust duct. The error in activity determination is estimated at 10% based on acceptance criteria for the daily dose calibrator constancy checks.

Response to questions on Charcoal filtration effectiveness for ^{18}F labeled FDG production

April 18, 2008

Carbon filter systems can be used to effectively reduce the emissions of ^{18}F during production of FDG if properly sized for the volume of air that will be present. The first example shown will be from the Nottingham UK site, which utilizes the Coincidence Technologies chemistry module with a bag on the exhaust port, and a Calgon KEP3S system rated at a volumetric flow of 0.236 m3 per second. The filter system consists of one pre-filter, one HEPA filter, and two carbon filters, all in series. A drawing of the filter is given in Attachment 1. These filters are modular and can be constructed in many different configurations and sizes to accommodate various placement constraints as well as increased volumetric flow rates. The monthly release chart is shown in Table 1.

	January	February	March	April	May	June
Bq	3.45E+07	8.88E+07	3.84E+09	4.49E+09	2.82E+09	6.64E+08
MBq	3.45E+01	8.88E+01	3.84E+03	4.49E+03	2.82E+03	6.64E+02

	July	August	September	October	November	December	Total
Bq	7.41E+08	1.49E+08	1.97E+08	2.23E+08	1.21E+08	1.30E+09	1.19E+10
MBq	7.41E+02	1.49E+02	1.97E+02	2.23E+02	1.21E+02	1.30E+03	1.19E+04

Using this annual release and modeling a generic facility, an annual radiation dose at a location 22.86m from the release point results in an annual effective dose equivalent of 0.4 μSv. Building parameters assumed are a release height of 12m, building height of 3m, and a wind speed of 2m/s. The program used was the US EPA COMPLY computer code[1] that utilizes building parameters, gaussian dispersion, and basic meteorological data to calculate the effective dose.

Recently completed filter tests at a US facility, using the Explora chemistry module provides release fractions using the small carbon filter located on the Explora module exhaust alone, a KEP3S filter unit alone, no filters, and both units combined.

[1] http://www.epa.gov/radiation/assessment/comply.html

Week	Emissions (mCi) Average/day	F-18 (Ci) Produced Average/day	filtration type	release fraction
1	231	32.34	none	7.47
2	59	34.4	Explora Only	2.03
3	51	34.6	Explora Only	1.76
4	5	35.58	KEP3s + Explora	0.18
5	4	30.87	KEP3s + Explora	0.12
6	6	37.25	KEP3s + Explora	0.22
7	6	25.91	KEP3s + Explora	0.16
8	12	36.15	KEP3s only	0.43
9	15	32.87	KEP3s only	0.49
10	4	31.13	KEP3s + Explora	0.12

filtration type	ave release fraction	ave daily release (mCi)
none	7.47	231.00
Explora Only	1.90	55.00
KEP3s only	0.46	13.50
KEP3s + Explora	0.16	5.00

Using the same building and meteorological data as above, and 260 production days per year, the annual effective dose equivalent is 0.11 μSv.

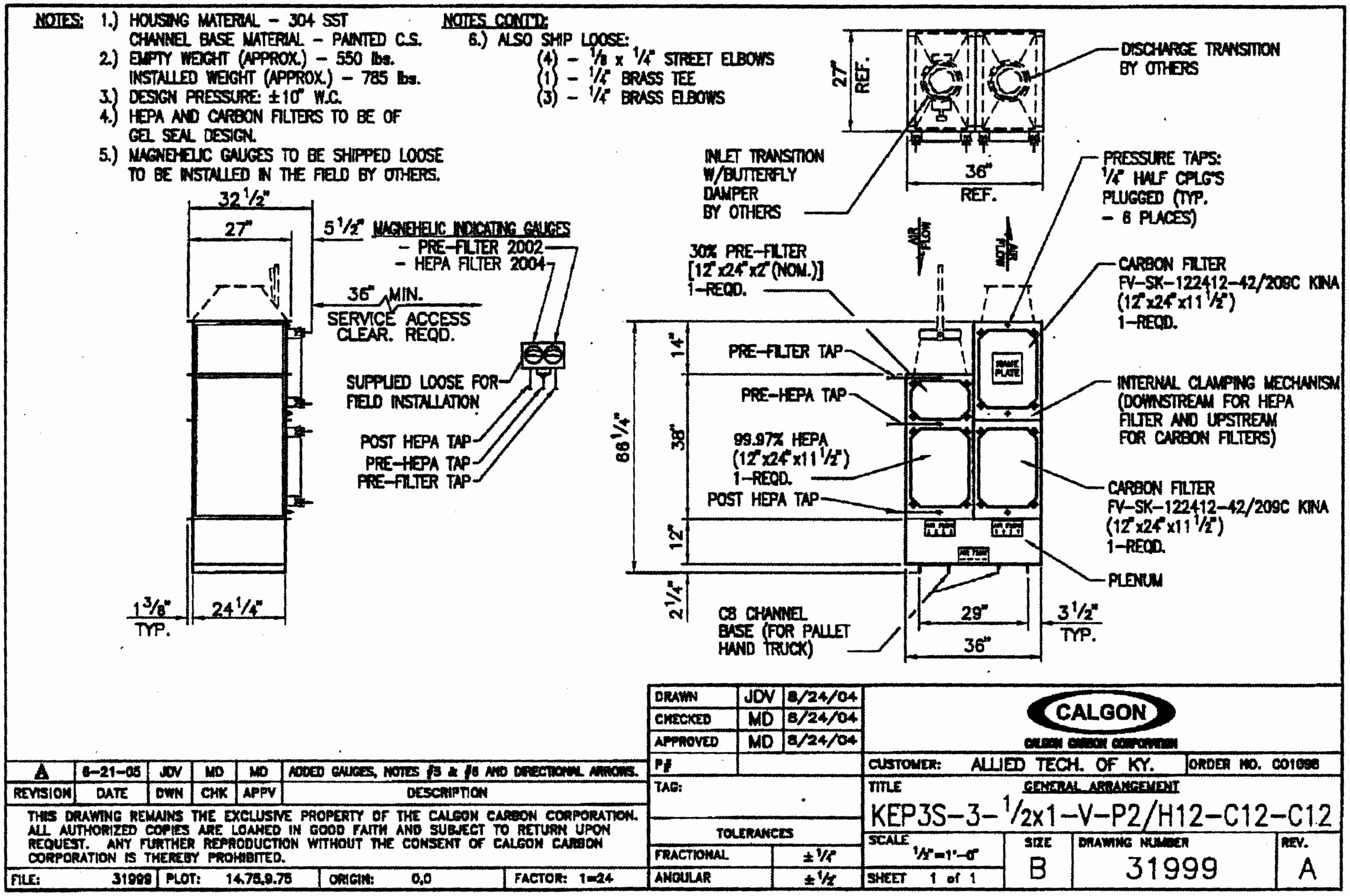
We would need site specific details to provide more precise calculations of the impact on radiation dose due to effluents from an FDG production facility. The COMPLY code was run on Level 3, which uses a very conservative wind data model. Actual windrose data can be used that will further reduce the effective dose equivalent.

Please do not hesitate to call or email with any questions on this brief report.

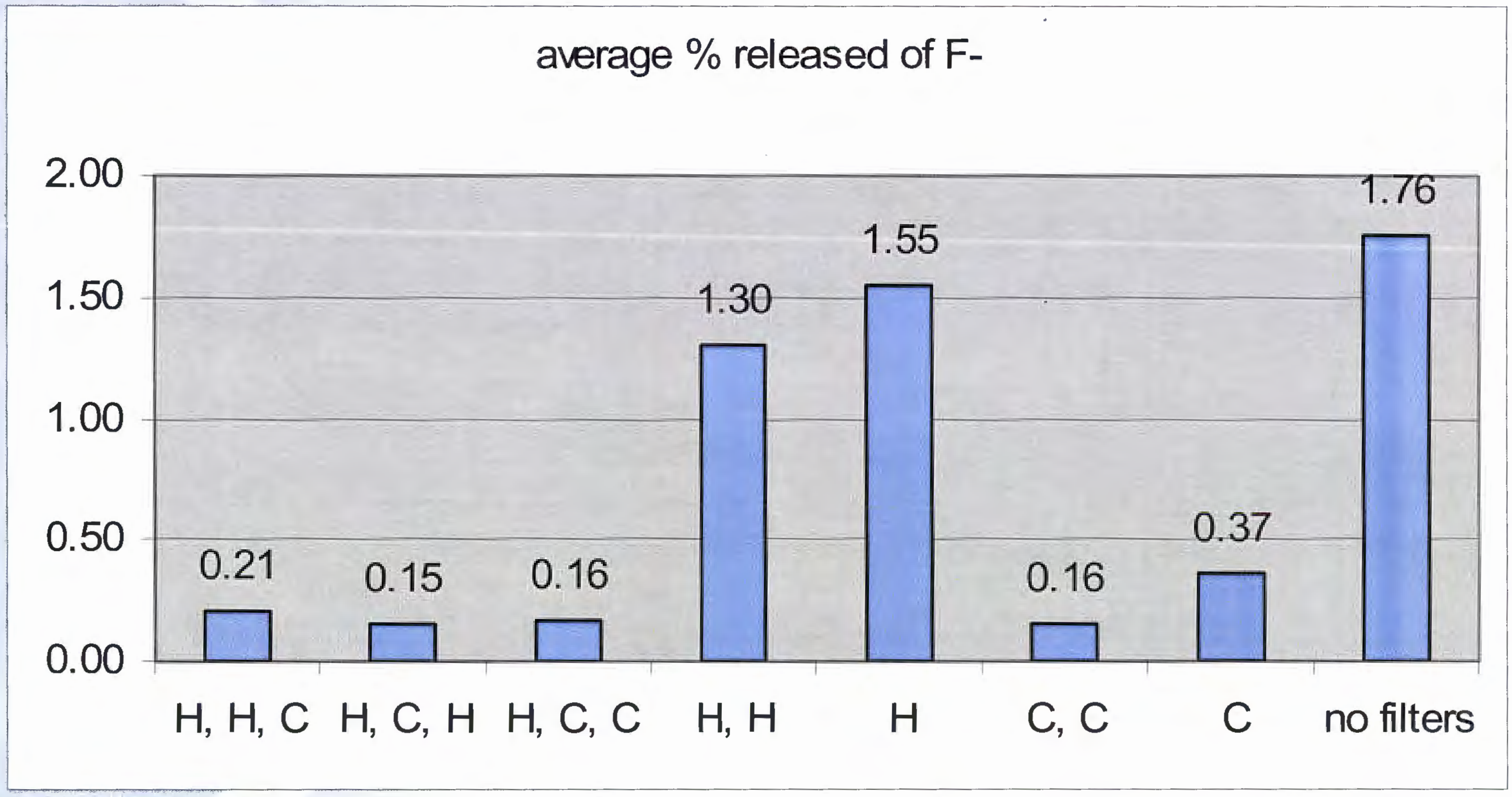
Sincerely,

Roger Moroney, CHP
Manager – Radiological Compliance
Siemens Molecular Imaging
865-218-2595
william.moroney@siemens.com

Attachment 1
KEP3S Filter diagram



New Filter Design Testing



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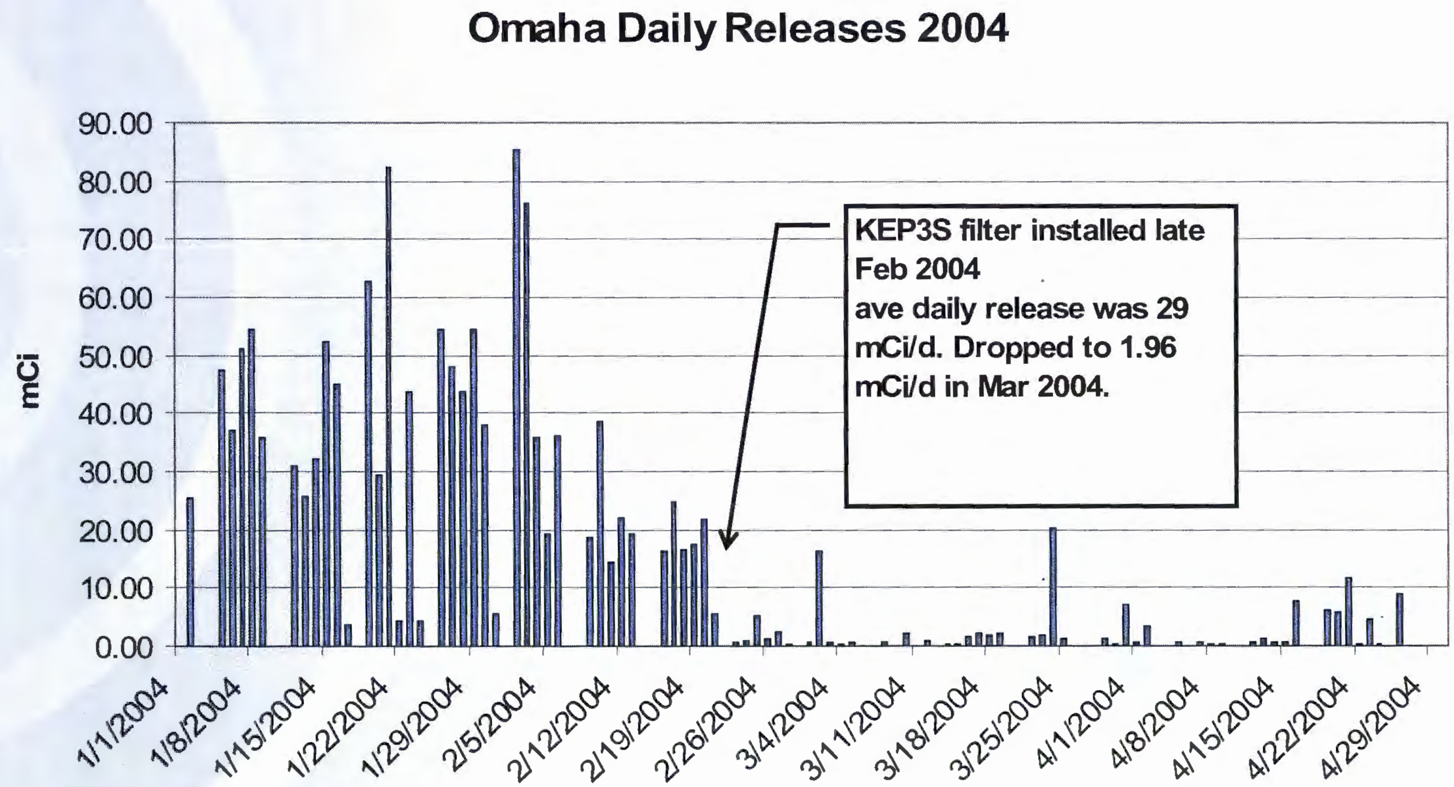
New Filter Design Results

- Result from Site With New KEP3S (Dallas) Filter Installed – 90% drop in total activity released

	Before (Jan – Feb)		After (Mar – Apr)	
	Daily Ave (mCi)	Two Month Total (mCi)	Daily Ave (mCi)	Two Month Total (mCi)
Omaha	29	1392	1.7	111

PETNET PHARMACEUTICALS, INC.

New Filter Design Results



PETNET PHARMACEUTICALS, INC.

2800 Solway Road
Knoxville, TN 37931

Calibration Certificate

Calibration Certificate for CF-901,Serial # 19901, Bar Code # ,Property # SEC-7013

Date: 03/04/13 **Date Last Cal. Expires:** **Technician:** Jeffrey Knight

Location: 9999, **Reason For Calibration:** Initial Calibration

EQUIPMENT USED DURING CALIBRATION

MODEL: D-814 **SERIAL #:** 3114 **CAL. DUE:** 09/21/13

MODEL: **SERIAL #:** **CAL DUE:**

AS FOUND DATA **AF Physical Condition** SAT **AS LEFT DATA**

As Found Instrument Flow Indication: 12 **CFM** **As Left Instrument Flow Indication:** 12 **CFM**

As Found Calibrator Flow Indication: 12 **CFM** **As Left Calibrator Flow Indication:** 12 **CFM**

Unit of Measure: ○ **LPM** ◉ **CFM**

Reproducibility 12 **CFM** 12 **CFM** 12 **CFM** **Average:** 12.00 **CFM**

☑ **Are the Individual Counts Within 10% of the Average?**

CALIBRATION DATA	TARGET VALUE	AIR SAMPLER READING	CALIBRATOR READING	ERROR %
	2.00 CFM	2.00 CFM	1.97 CFM	1.50% CFM
	6.00 CFM	6.00 CFM	5.84 CFM	2.67% CFM
	12.00 CFM	12.00 CFM	11.40 CFM	5.00% CFM

Air Sampler Setting 12.00 ☑ **Is Error Within 10%?**

Reproducibility 12 **CFM** 12 **CFM** 12 **CFM** **Average:** 12.00 **CFM**

☑ **Are the Individual Counts Within 10% of the Average?**

Air Sampler rotometer reading: ◉ Use Manufacturers Indication ○ Use Corrected Marking ○ N/A

Comments: **Married as a set with:** **Model** **Bar Code #:**

Calibrated using F&J Model #FP-47M filter media.

☑ **Does Instrument Meet Final Acceptance Criteria?** ☑ **Calibration Sticker Attached?**

Date Instrument is Due For Next Calibration: 03/04/14

Performed by: [signature] **Reviewed by:** [signature] **Date:** 3/4/14

Printed Name: Jeffrey Knight

Safety and Ecology Corporation
2800 Solway Road
Knoxville, TN 37931

Calibration Certificate

Calibration Certificate for CF-901,Serial # 19900, Bar Code # ,Property # SEC-7012

Date: 03/04/13 **Date Last Cal. Expires:** **Technician:** Jeffrey Knight

Location: 9999, **Reason For Calibration:** Initial Calibration

EQUIPMENT USED DURING CALIBRATION

MODEL:	D-814	**SERIAL #:**	3114	**CAL. DUE:**	09/21/13
MODEL:		**SERIAL #:**		**CAL DUE:**	

AS FOUND DATA **AF Physical Condition** SAT **AS LEFT DATA**

As Found Instrument Flow Indication: 11.5 **CFM** **As Left Instrument Flow Indication:** 11.5 **CFM**

As Found Calibrator Flow Indication: 11.5 **CFM** **As Left Calibrator Flow Indication:** 11.5 **CFM**

Unit of Measure: ○ **LPM** ◉ **CFM**

Reproducibility 11.5 **CFM** 11.5 **CFM** 11.5 **CFM** **Average:** 11.50 **CFM**

☐ **Are the Individual Counts Within 10% of the Average?**

CALIBRATION DATA	**TARGET VALUE**	**AIR SAMPLER READING**	**CALIBRATOR READING**	**ERROR %**
	2.00 **CFM**	2.00 **CFM**	1.88 **CFM**	6.00% **CFM**
	6.00 **CFM**	6.00 **CFM**	5.94 **CFM**	1.00% **CFM**
	11.50 **CFM**	11.50 **CFM**	11.40 **CFM**	0.87% **CFM**

Air Sampler Setting 11.50 ☑ **Is Error Within 10%?**

Reproducibility 11.5 **CFM** 11.5 **CFM** 11.5 **CFM** **Average:** 11.50 **CFM**

☐ **Are the Individual Counts Within 10% of the Average?**

Air Sampler rotometer reading: ◉ Use Manufacturers Indication ○ Use Corrected Marking ○ N/A

Comments: **Married as a set with:** **Model** **Bar Code #:**

Calibrated using F&J Model #FP-47M filter media.

☑ **Does Instrument Meet Final Acceptance Criteria?** ☑ **Calibration Sticker Attached?**

Date Instrument is Due For Next Calibration: 03/04/14

Performed by: [signature] **Reviewed by:** [signature] **Date:** 3/04/13

Printed Name: Jeffrey Knight

From: (865) 218-2595 Origin ID: RKWA
Roger Moroney
PETNET Solutions, Inc.
810 Innovation Drive

Knoxville, TN 37932

FedEx Express

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Ship Date: 29MAR13
ActWgt: 1.0 LB
CAD: 101635228/INET3370

Delivery Address Bar Code

SHIP TO: (630) 829-9854 BILL SENDER
Kevin Null
US Nuclear Regulatory Comm. RIII
2443 WARRENVILLE RD STE 210

LISLE, IL 60532

Ref # Indianapolis 50-938
Invoice #
PO #
Dept #

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