PETNET Solutions

November 21, 2016

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

Re: Additional information for CNs 591632 and 591633

Dear Mr. Parker:

Enclosed is a response to your request for additional information regarding our amendment request.

If you have any further questions concerning this letter, please contact me at the number below or Elizabeth Gillenwalters at elizabeth.gillenwalters@siemens.com or 865-218-3295.

Sincerely,

Roger Moroney, CHP
Senior Manager of Radiation Protection/EHS
Molecular Technologies Division of PETNET Solutions, Inc.
(865) 201-7009 mobile
(865) 218-2595 office
william.moroney@siemens.com

att: Response for Request for Additional Information

cc: Joel Readinger, R.Ph. RSO PETNET Indianapolis

RECEIVED NOV 22 2016

Request for Additional Information:

1) **Please confirm that you will implement the manufacturer's calibration procedure and describe the frequency of the calibration.**

Response

Siemens and Ultra have worked together to develop a technical report on calibration of positron gas stack monitoring systems as well as a technical presentation at the 61^{st} Annual Meeting of the Health Physics Society in July 2016. A copy of this technical presentation is provided as Attachment 1. The methodology of this technical report will be used to calibrate the stack monitoring system using a series of gas releases into the system of known activity, which will be measured utilizing a calibrated dose calibrator. System response to the known activity will be utilized to calculate a site specific calibration factor. This gas release procedure will be performed after initial installation as well as whenever the quarterly calibration check indicates recalibration is necessary.

A quarterly calibration check using a sealed source will be performed to verify the system is responding within 10% of the site specific calibration factor. The manufacturer provides a procedure for this calibration check.

2) **Please identify the radionuclide(s) that will be used to calibrate the monitor, and describe how you will determine the activity of the nuclide(s) that is used (i.e., NIST-traceable, etc.); and**

Response

C-11 is utilized for the gas release procedure, as this nuclide is a positron emitter with a shorter half-life than the site's radionuclide of concern F-18. The activity of the gas released will be determined utilizing a calibrated dose calibrator. The dose calibrator is calibrated with a NIST traceable Cs-137 vial source.

A NIST traceable Cs-137 check source will be utilized for the annual calibration check described above.

3) **Please provide a calculation and/or other description regarding the MDA/MDC of the detector and how this compares to the 10 CFR Part 20 limits for air effluent concentration. Also, please indicate if these are "real-time" results.**

Response

PETNET assesses public doses from effluents in accordance with 10 CFR 20.1302(b)(1) via the COMPLY program. Each Ultra system has real-time data alarm set points for daily, monthly and yearly effluent release and the value of these set points is such to ensure compliance with the 10 mrem constraint limit based on site historical data.

The yearly effluent release alarm set point for the Indianapolis site is currently 13 Ci. A COMPLY report for this theoretical release value is provided as Attachment 2 showing an effective dose equivalent at COMPLY level 4 of 8 mrem per year. The daily and monthly effluent release alarm points are set at incremental values of this yearly effluent alarm value.

While calculation and use of a MDC is not utilized by PETNET for demonstration of compliance, the manufacturer provides the following equation to determine the MDC, in units of picocurie per milliliter, of the detector:

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

Where,

B = Background count rate (counts per second)
T = Measurement time (seconds)
E = Efficiency parameter (picocurie per milliliter per counts per second).

ATTACHMENT 1

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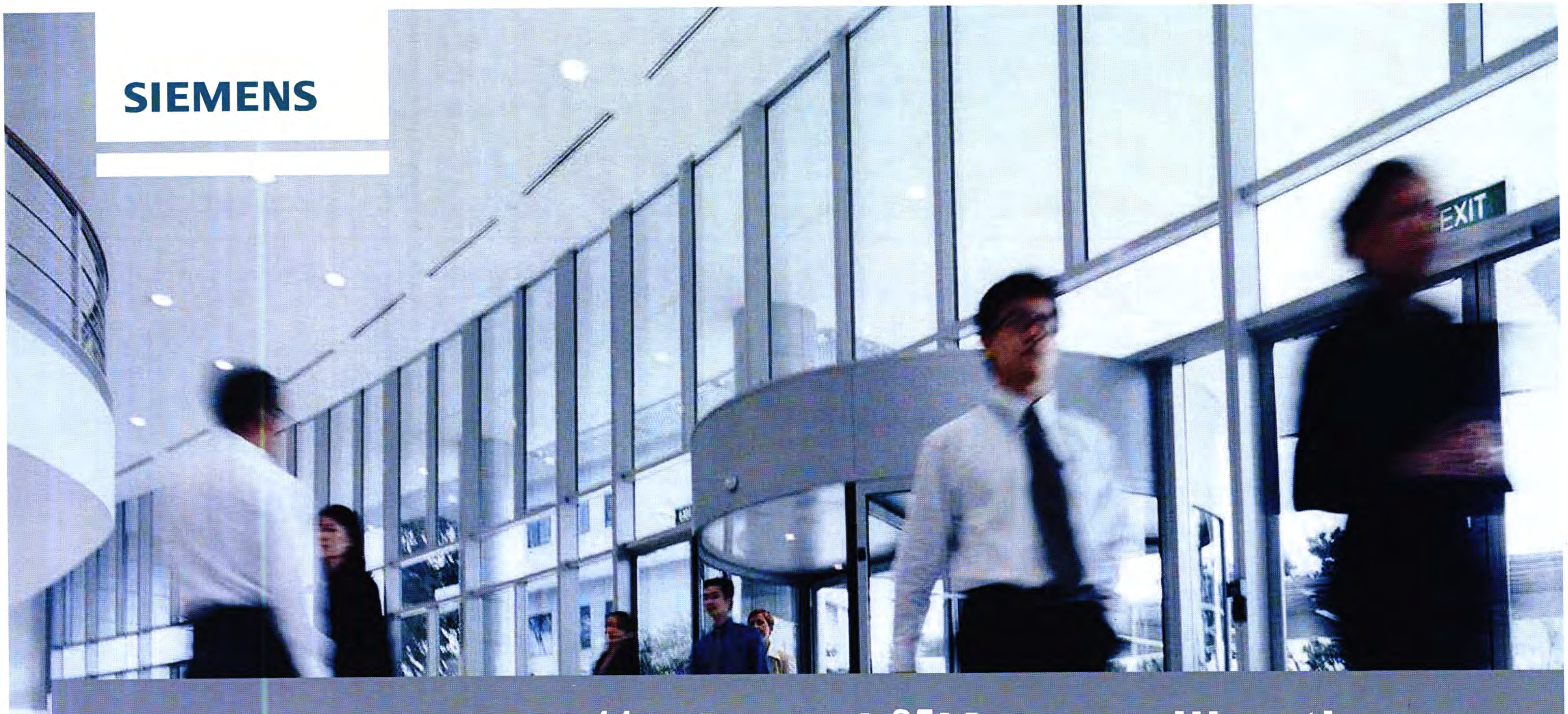

A comparison of $^{11}CO_2$ and ^{85}Kr as calibration gases for a beta-detecting stack monitor for PET manufacturing facilities.

DJ Krueger[1], WR Moroney[1], FL Plastini[1]. JM Parkin[2]
1 Siemens/PETNET, 2 Ultra Electronics

Answers for life.

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Topics

- Background
- Calibration Process
- Monte Carlo Simulations – ^{11}C and ^{85}Kr Comparison
- ^{11}C Calibration Results
- ^{85}Kr Calibration Results
- Comparison of calibration factors
- Solid source performance check
- Conclusions
- Notes on Uncertainty Analysis

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PET Nuclide Stack Monitor Calibration Issues

- ^{18}F is the major nuclide in PET drug manufacturing. It is ~~extremely~~ volatile as produced in the $^{18}O(p,n)^{18}F$ reaction and thus must be monitored.
- Full system calibration is difficult with ^{18}F due to its reactivity.

- Other positron radionuclides can be used, e.g., $^{11}CO_2$, but
  - this is not possible to produce at all locations (special targets)
  - higher energy compared to ^{18}F ($^{+}\beta_{max}$ = 960 keV instead of 634 keV)

- Potential Solution: Use a non-reactive, beta emitting gas for a calibration
  - ^{85}Kr is ideal, as it is readily available and very similar emission energy to ^{18}F (β_{max} = 687 keV compared to 634 keV)
  - Also has a long half life, meaning errors in activity due to decay are negligible.

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General Calibration Process

- Remove any filters that would hold up the passage of gas from release point to detectors

- Quantify a bolus of gas
  - $^{11}CO_2$ is loaded to a 60 ml syringe and measured in a Dose Calibrator (IC)
  - ^{85}Kr in pressurized cylinder. Use Ideal Gas Law: $PV = nRT$

- Collect response of detectors for release of bolus

- Modify the calibration factors so that released activity is what the system reports

Ultra Electronics (Lab Impex) PET Monitor Calibration Procedure

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- Set calibration factor to unity in the monitor
  - Calibration factor is in units of pCi/ml per cps (dimensionally m^{-3})
- Quantify gas activity
- Release activity
- Record concentration result and discharge in the logging software
- The ratio of the calibrated release activity to the discharge reported after each release gives the calibration factor

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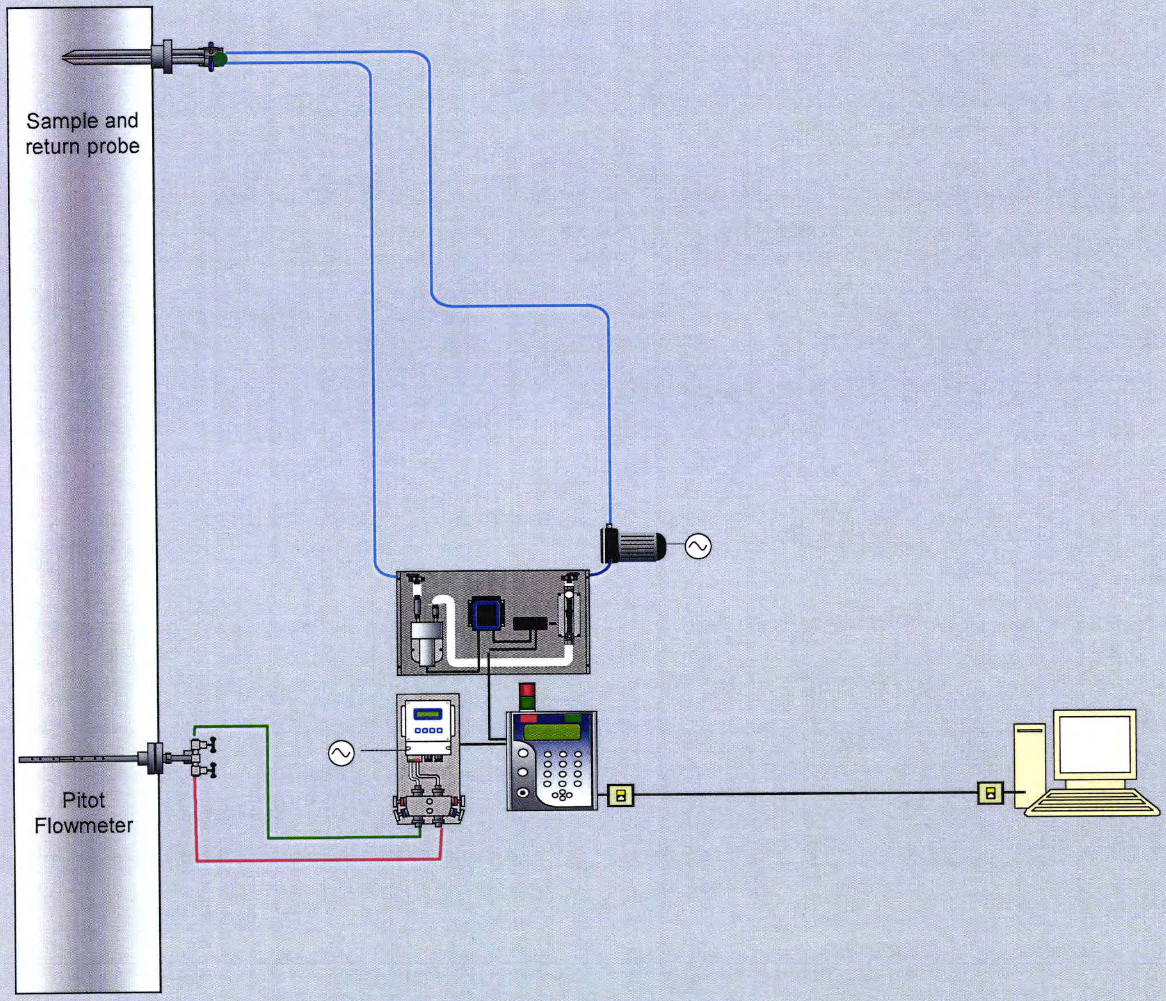
Stack monitoring system



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Monte Carlo Simulation Results for ^{18}F, ^{11}C and ^{85}Kr

- Monte Carlo simulation of the detector response to ^{18}F, ^{11}C and ^{85}Kr was performed
- Simple model of the gas chamber, and detector, with an assumed mix of air containing radioactive gas
- The model included the annihilation photons from the positron gases
- Energy bins in the simulation were in intervals of 25 keV

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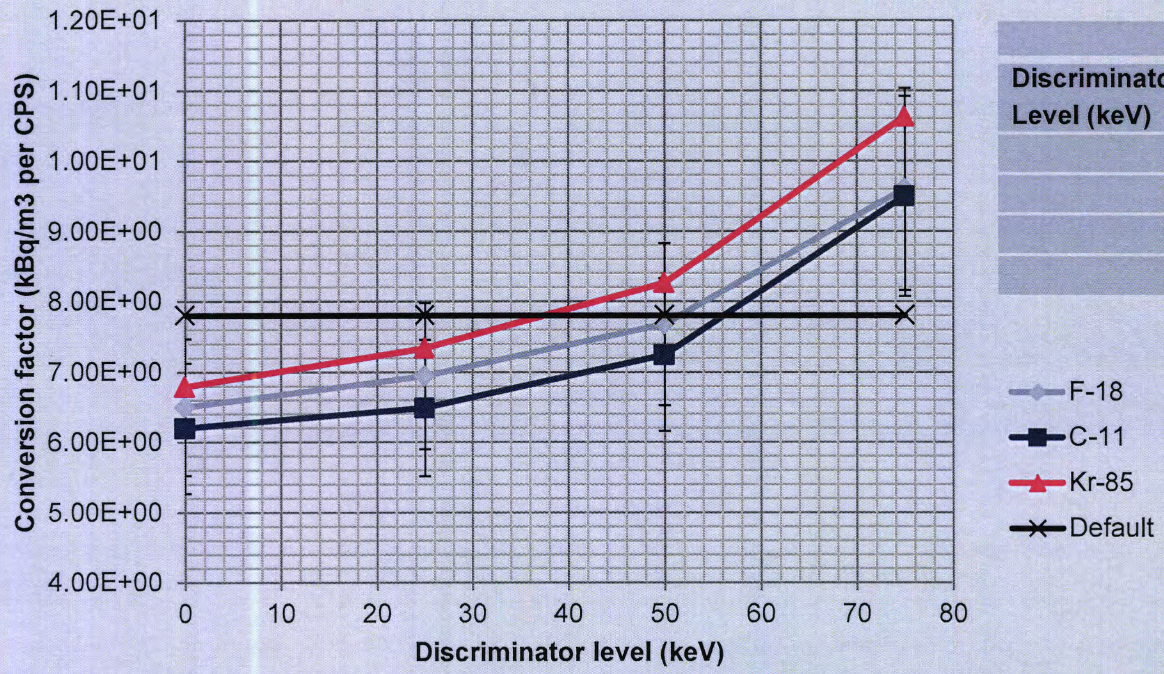
Monte Carlo Simulation Results for ^{18}F, ^{11}C and ^{85}Kr



	Conversion factor (kBq/m3 per CPS)		
Discriminator Level (keV)	18F Positron	11C Positron	85Kr Beta
0	6.50	6.20	6.79
25	6.94	6.49	7.33
50	7.67	7.24	8.26
75	9.60	9.50	10.6

- Simulations suggest a slightly lower efficiency with ^{85}Kr
- The difference is expected to be approximately 10-15 %
- The expected sensitivity to ^{85}Kr is close enough to make it a viable alternative

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Calibration Comparison – Loma Linda.

Answers for life.

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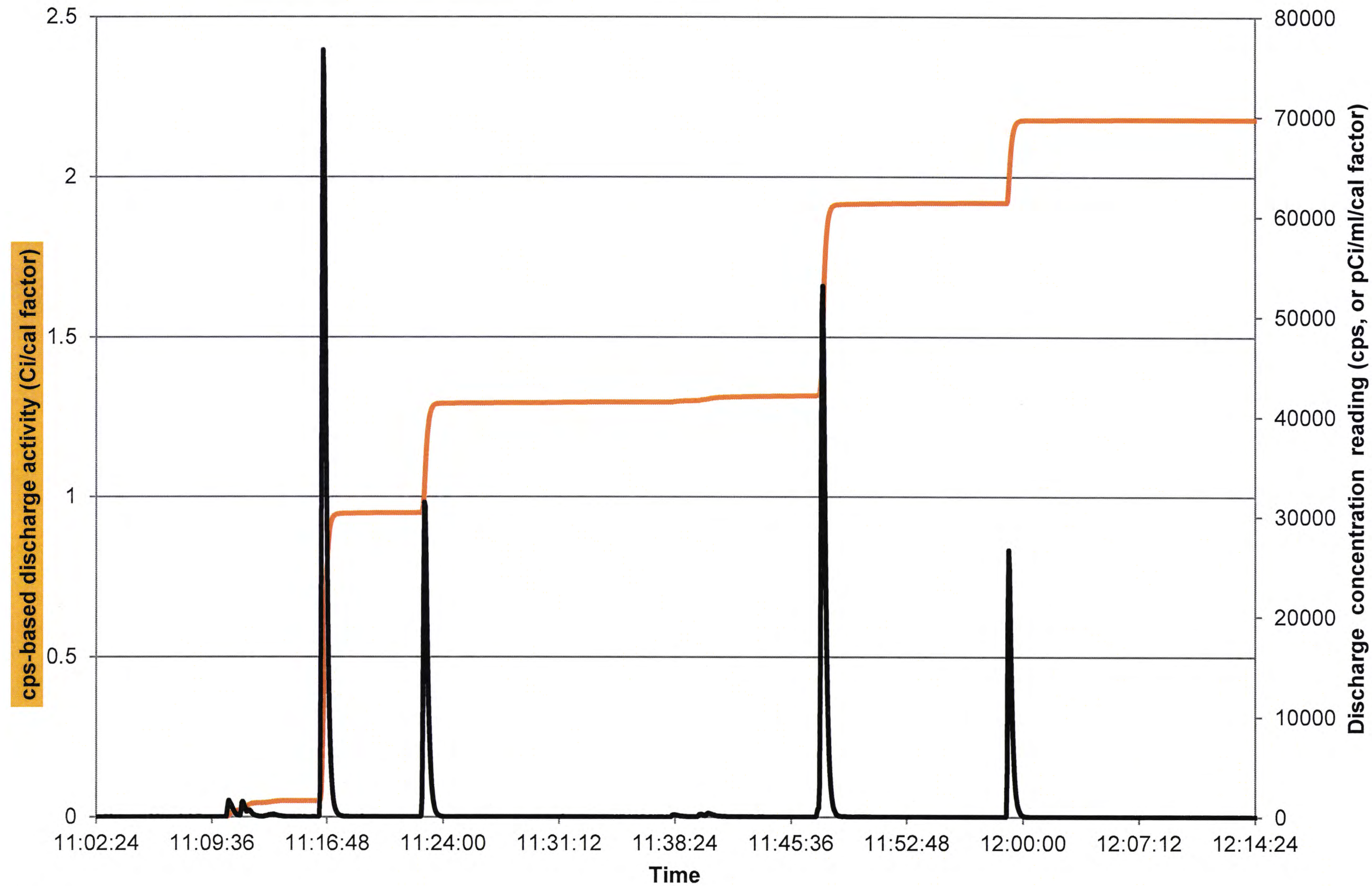
^{11}C Calibration Releases (4 separate releases)



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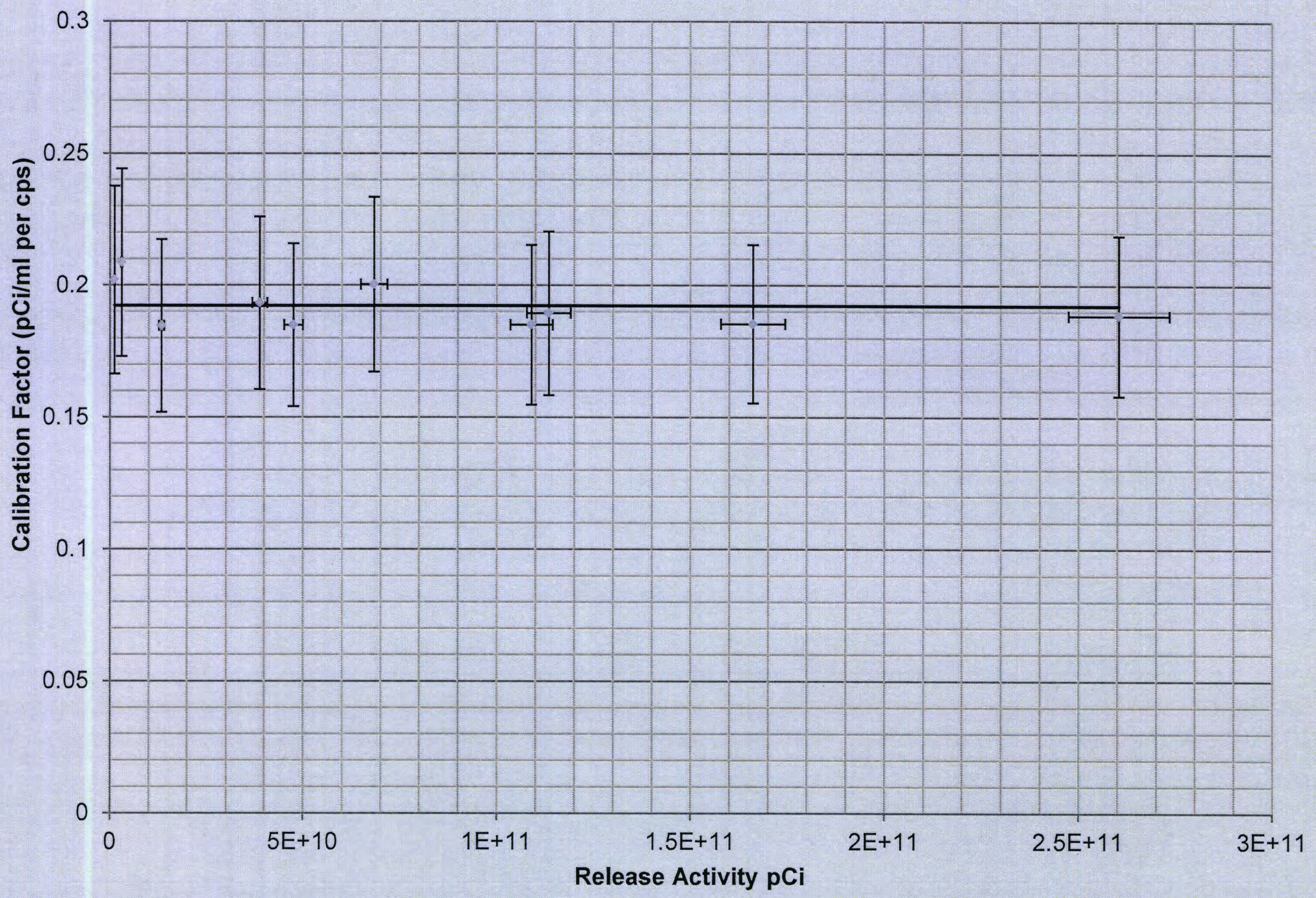
^{11}C Calibration Data



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^{11}C Calibration Data

Release No.	Release Activity Ci	Release Activity MBq	Ratio (cal factor) for pCi/ml	Ratio (cal factor) for kBq/m^3	Uncertainty in Cal. Factor (%)
1	0.1662	6149.4	0.185	6.845	15.7
2	0.0684	2530.8	0.200	7.400	15.9
3	0.1135	4199.5	0.189	6.993	15.8
4	0.0477	1764.9	0.185	6.845	15.9
5	0.0390	1443.0	0.193	7.141	16.0
6	0.0134	495.8	0.185	6.845	16.2
7	0.2605	9638.5	0.189	6.993	15.7
8	0.1090	4033.0	0.185	6.845	15.8
9	0.0031	114.7	0.209	7.733	17.0
10	0.0012	44.4	0.202	7.474	17.6
MEAN			0.192	7.11	16.8

- Mean Cal factor of 0.19 ± 0.03 (pCi/ml per cps)
- All results sit comfortably inside the uncertainty – dominated by systematic error

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^{85}Kr Gas Setup

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^{85}Kr Procedure

- Two cylinders with identical volume and nominally identical activity
- Release one cylinder completely (1 atm left)
- Connect the two cylinders and equalize pressure, essentially halving activity in each. Verify with pressure gauge
- Release one cylinder
- Reconnect both cylinders and equalize
- Repeat

^{85}Kr Calibration Releases 1-6

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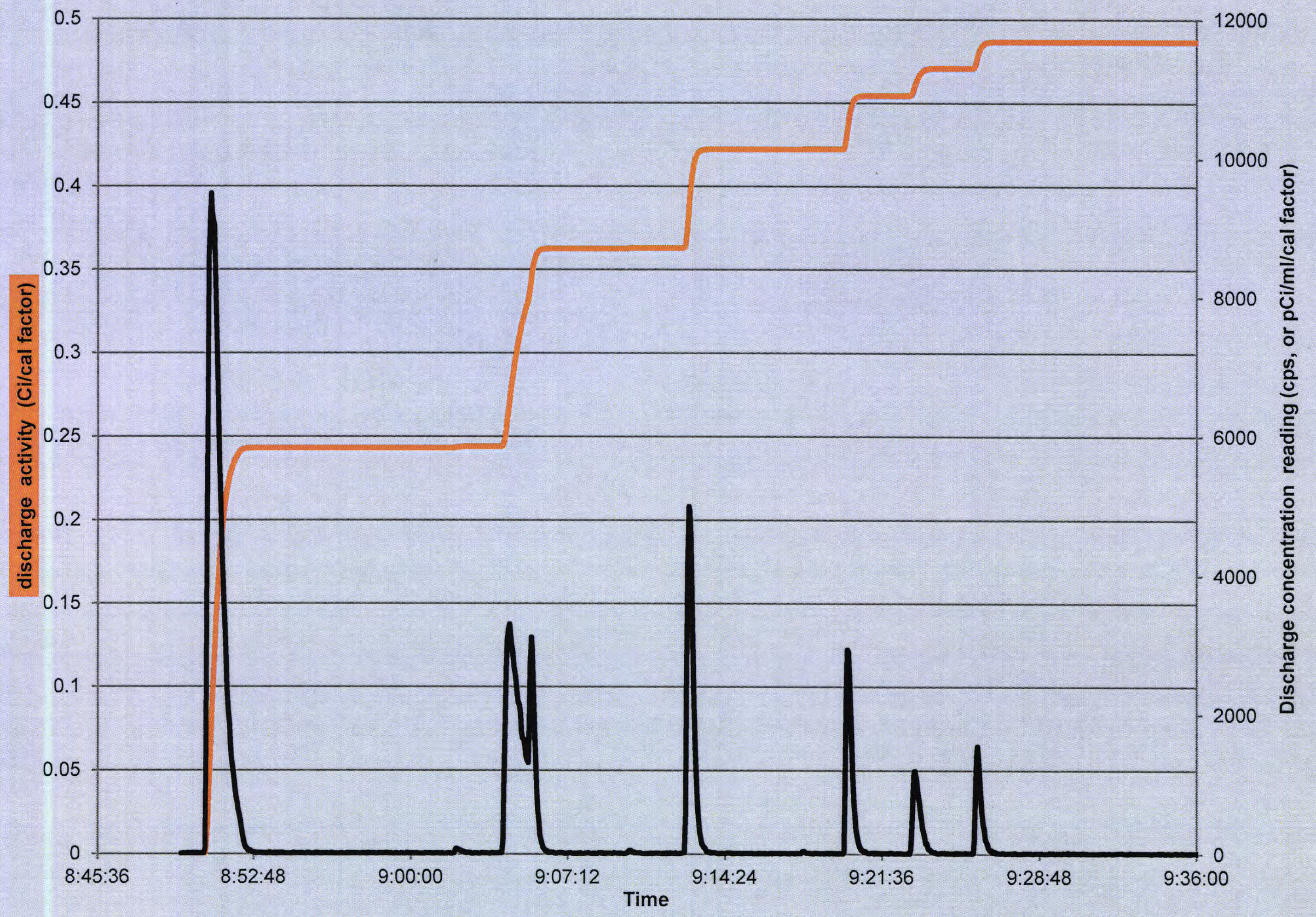
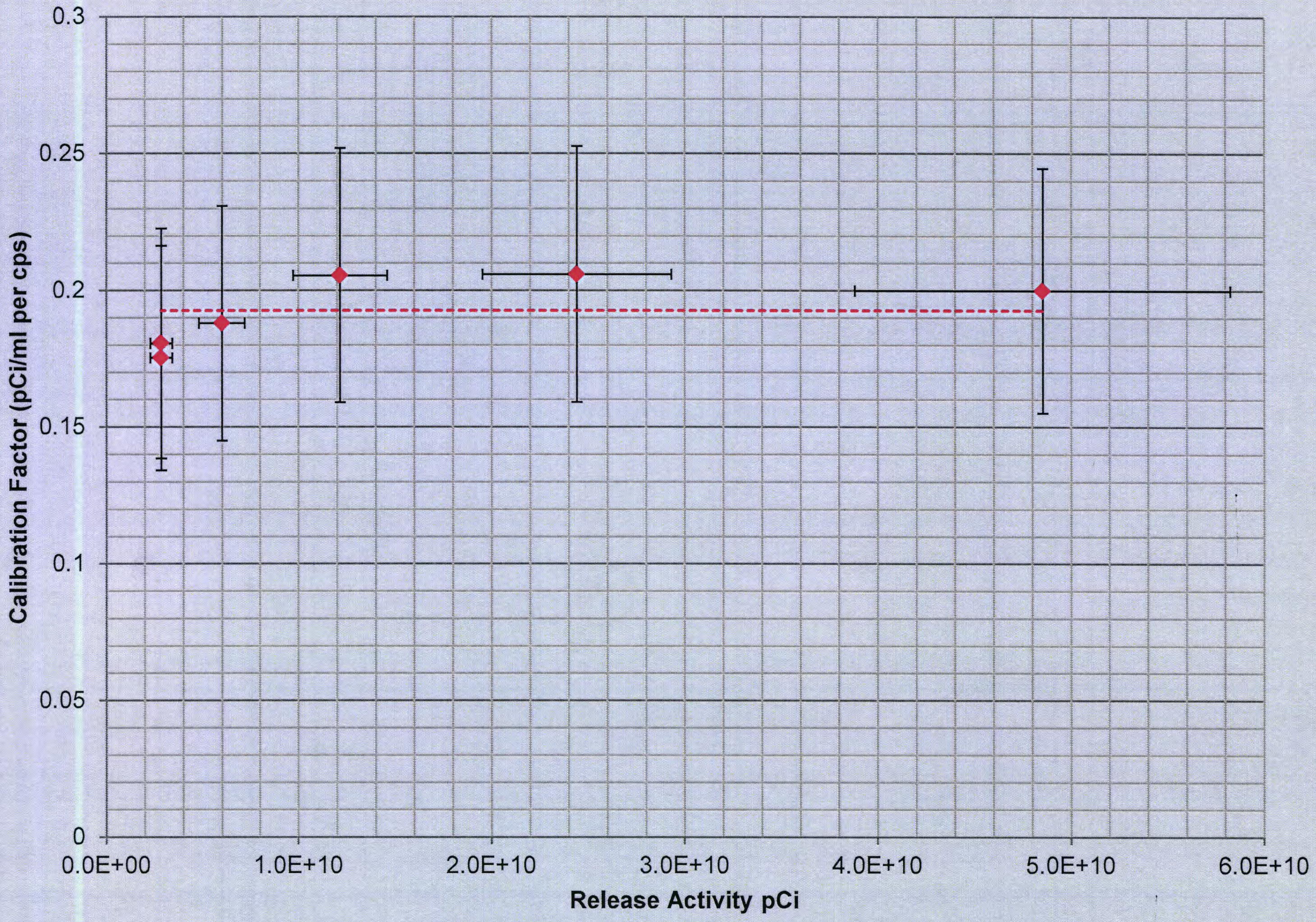


^{85}Kr calibration data



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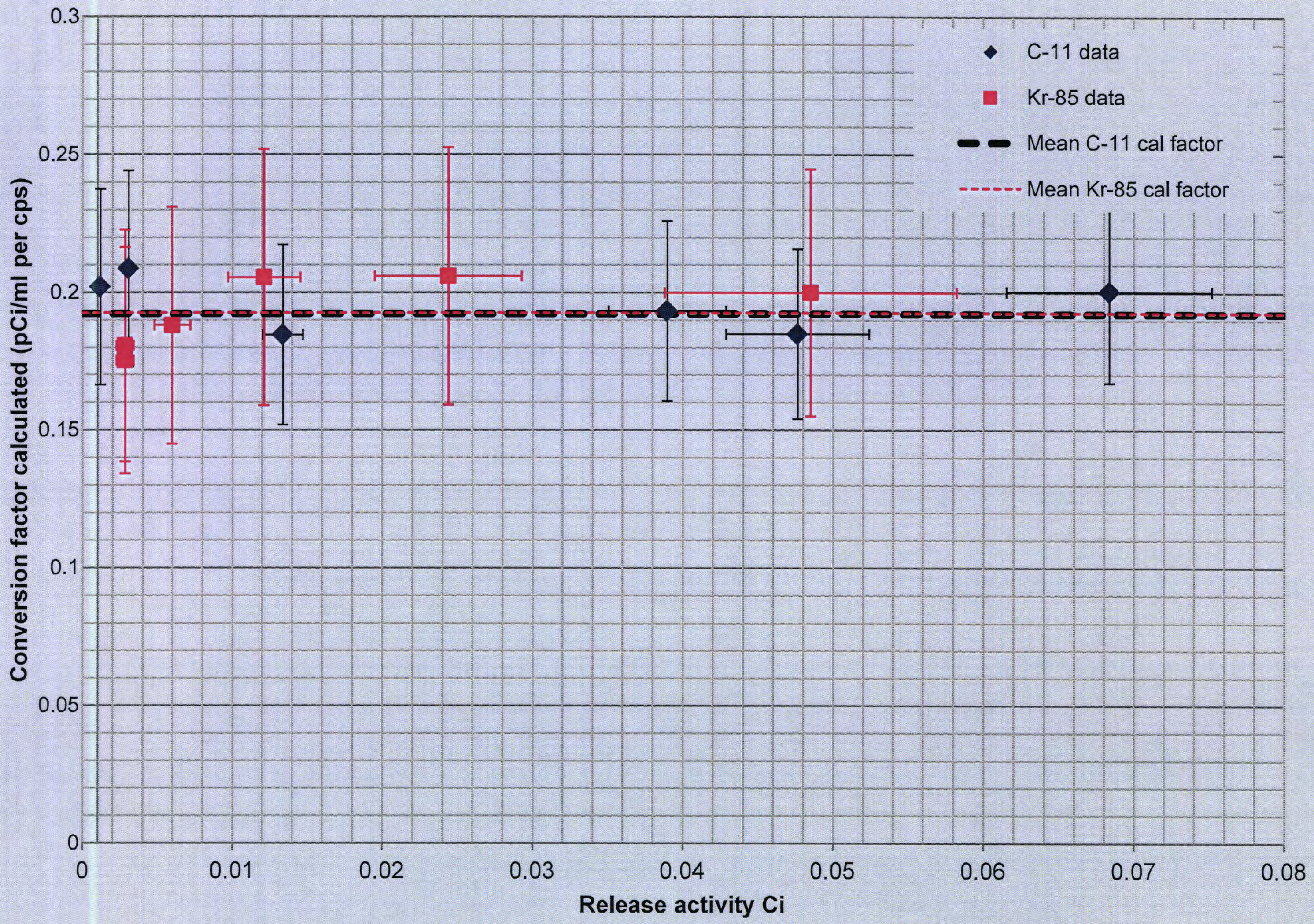
^{85}Kr calibration data

Release No.	Release Activity Ci	Release Activity MBq	Ratio (cal factor) for pCi/ml	Ratio (cal factor) for kBq/m^3	Uncertainty in cal factor (%)
1	0.04855	1796	0.200	7.400	22.4
2	0.02443	903.9	0.206	7.622	22.7
3	0.01217	450.3	0.205	7.585	22.6
4	0.00601	222.4	0.188	6.956	22.9
5	0.00286	105.8	0.175	6.475	23.5
6	0.00286	105.8	0.181	6.697	23.3
MEAN			0.193	7.12	22.9

- Mean Cal factor of 0.19 ± 0.04 (pCi/ml per cps)
- Systematic error dominates again
- Errors are slightly larger in these results due to the starting uncertainty on the activity in the cylinders

^{11}C and ^{85}Kr calibration data



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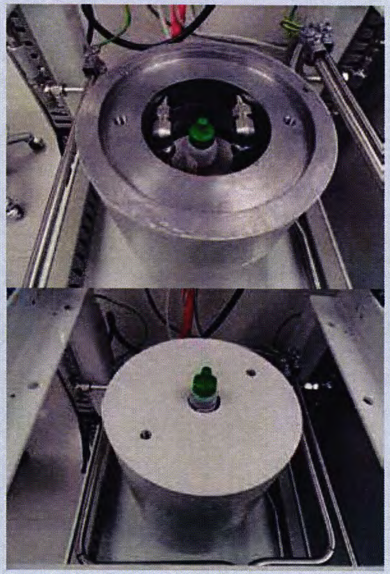
Solid source performance check

- A solid ^{137}Cs source reading was also taken to enable a cross check of detector performance against system performance to be analyzed for all future calibrations
- It is expected that gamma source response will be closely correlated to system gas calibration factor
- This will be assessed at future calibrations, both on this site, and at other sites to enable us to consider the viability of a solid source performance check
- Potential advantage that source checks could be performed and reduce the regularity of gas release calibrations



Check Source Position	Mean cps reading	Mean error cps	Mean error %	Mean cps/µCi (dead time corrected)
1	3271.6	38.4	1.2	16.3
2	298.7	11.7	3.9	1.49

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Conclusions

- The ^{85}Kr Mean Cal factor of 0.19 ± 0.04 (pCi/ml per cps) is in very close agreement with the ^{11}C factor of 0.19 ± 0.03
- The 15 % difference expected from simulations is not seen, but this is within the uncertainty of the measurements
- The results show real promise of the method to gain a calibration factor for the system using ^{85}Kr, where ^{11}C is not available
- Simulated results agree with experimental data when the uncertainties are taken into account
- A check source response was also obtained and will be used for correlation against gas calibrations in future

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Further Work

- There are plans for calibration releases of ^{11}C and ^{85}Kr at other sites, to assess the consistency of the results shown here
- Check source responses will also be obtained and compared against those presented here
- Future work will be used to standardize the calibration technique, and optimize the ^{85}Kr gas release procedure
- When more data are available, the case for solid source performance checks will be assessed and presented, with a view on periodicity of gas release calibrations and solid source checks
- Finally, when enough calibration data is available, the release data will be used to more fully validate the Monte Carlo model results.

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Note on uncertainty calculations for the Cal. Factor

The uncertainties are based on the combined uncertainties of each measurement, including stack flow, detector count rate, calculated discharge and release activity:

- Stack flow
- Detector count rate (statistical variation)
- Discharge calculation uncertainties (combination of the above)
- Released activity uncertainty

These are combined to give an overall uncertainty on the calculated Calibration Factor.

Each uncertainty calculation is detailed in the following slides.

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Note on uncertainty calculations for the Cal. Factor

- Stack flow
  - uncertainty calculated by combining the uncertainties in calibration measurement using a standard pitot (dP), ambient pressure (P) and temperature (T), to give an uncertainty (%) of each stack flow reading

$$Stack\ Flow = kA\sqrt{\frac{2dP}{\rho}}$$

  - Where: k is a calibration constant, A is stack area
  - ρ is calculated from the density of air at STP, and measured pressure and temperature in the stack.

$$\rho = \frac{\rho_{STP} T_{STP} P_{stack}}{P_{STP} T_{stack}}$$

  - The associated uncertainty in ρ is:

$$\frac{\Delta\rho}{\rho} = \frac{\Delta P_{stack}}{P_{stack}} + \frac{\Delta T_{stack}}{T_{stack}}$$

Note on uncertainty calculations for the Cal. Factor

- The stack flow fractional uncertainty is therefore:

$$Stack\ Flow = kA\sqrt{\frac{2dP}{\rho}}$$

$$\frac{\Delta Stack\ Flow}{Stack\ Flow} = \frac{1}{2}\left(\frac{\Delta dP}{dP} + \frac{\Delta\rho}{\rho}\right)$$

- Statistical variation in count rate of the detector
  - Based on the averaging time in the monitor and the count rate from the detector at the 95 % confidence level:

$$\sigma_{cps} = \frac{1.645\sqrt{cps \times t_{averaging}}}{t_{averaging}}$$

- This makes the fractional uncertainty σ_{cps}/cps

Note on uncertainty calculations for the Cal. Factor

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- Discharge Uncertainty
  - This is a combination of the above errors (stack flow and detector statistical variation)
  - The discharge calculation (simplified) is:

$$Reported\ discharge(pCi) = \sum_{t=0}^{t=end} detector\ reading\left(\frac{pCi}{ml}\right) \times stack\ flow\left(\frac{ml}{s}\right)$$

  - When the Cal factor is set to 1, the detector reading is actually cps, and will result in the reported discharge being out by a factor equal to the correct Cal. Factor.
  - The fractional uncertainty on this is:

$$\frac{\Delta Reported\ discharge(pCi)}{Reported\ discharge(pCi)} = \sum_{t=0}^{t=end}\left(\frac{\sigma_{cps}}{cps} + \frac{\Delta Stack\ Flow}{Stack\ Flow}\right)$$

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Note on uncertainty calculations for the Cal. Factor

- Gas activity uncertainty (ΔA)
  - uncertainty based on either the calculated ^{11}C activity from measurement and decay correction, or from the initial uncertainty of stated activity in the ^{85}Kr bottles. A fixed uncertainty of 10 % is assumed for the measured ^{11}C activity, and 20 % is taken for the ^{85}Kr, based on the source supplier's stated uncertainty on the activity contained within the bottles. This means ΔA/A is taken as 0.1 for ^{11}C and 0.2 for ^{85}Kr.

- The Cal Factor (CF) is calculated from the equation:

$$CF = \frac{Released\ Activity}{Reported\ Discharge}$$

- And the associated uncertainty, using previously calculated values is:

$$\frac{\Delta CF}{CF} = \frac{\Delta A}{A} + \frac{\Delta Reported\ discharge(pCi)}{Reported\ discharge(pCi)}$$

ATTACHMENT 2

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 - V1.7.

Prepared by:

PETNET Solutions
PETNET Indianapolis
Indianapolis, IN

Prepared for:

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

PETNET Indianapolis 13 Ci

SCREENING LEVEL 4

DATA ENTERED:

Nuclide		Release Rate (curies/YEAR)
F-18	D	1.300E+01

Release height 10 meters.

Building height 8 meters.

The source and receptor are not on the same building.

Building width 22 meters.

Building length 21 meters.

STACK DISTANCES, FILE: indydis

DIR	Distance (meters)
N	68.6
NNE	183.0
NE	119.0
ENE	73.2
E	73.2
ESE	73.2
SE	91.4
SSE	128.0
S	64.0
SSW	76.2
SW	97.5
WSW	128.0
W	24.4
WNW	25.9
NW	14.9
NNW	70.1

WINDROSE DATA, MODIFIED FILE: indywind

Source of wind rose data: Indianapolis International Airport

Dates of coverage: 1992
Wind rose location: Airport
Distance to facility: 20 miles

Percent calm: 0.03

Wind FROM	Frequency	Speed (meters/s)
N	0.058	4.41
NNE	0.047	4.24
NE	0.050	4.42
ENE	0.034	4.54
E	0.037	4.44
ESE	0.050	4.08
SE	0.059	4.23
SSE	0.049	4.08
S	0.061	4.33
SSW	0.067	4.63
SW	0.111	4.69
WSW	0.099	4.72
W	0.049	4.84
WNW	0.061	5.14
NW	0.076	5.43
NNW	0.061	4.74

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 26. meters from the source in the WNW sector.

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

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

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

Input parameters outside the "normal" range:
None.

RESULTS:

Effective dose equivalent: 8.0 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 **********

ORIGIN ID:RKWA (865) 237-9045
ELIZABETH GILLENWALTERS
PETNET SOLUTIONS, INC.
810 INNOVATION DRIVE

KNOXVILLE, TN 37932
UNITED STATES US

SHIP DATE: 21NOV16
ACTWGT: 0.50 LB
CAD: 105091792/INET3790

BILL SENDER

TO BRYAN PARKER
US NUCLEAR REGULATORY COMM. RIII
MATERIALS LICENSING BRANCH
2443 WARRENVILLE RD STE 210
LISLE IL 60532
(678) 828-7050 REF:
INV:
PO: DEPT:

544J3/CBB1/14E8

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STANDARD OVERNIGHT

TRK# 0201 7777 6503 1164

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