PETNET Solutions

March 4, 2014

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

Re: C/N 580329 and questions regarding collection bag system for F-18 effluent release at PETNET St. Louis facility, RAM License No. 41-32720-03

Dear Mr. Null:

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

Concern 1

Describe the method used to purge/transfer F-18 gas to the collection bag during FDG and AV-45 production runs.

A. Include an estimate of the volume and radioactivity of F-18 gas that will be transferred to the collection bag during each production run.

B. Describe how you will ensure that the volume of the F-18 gas that is transferred to the collection bag is less than the volume of the collection bag.

Response 1

A. The method used to transfer ^{18}F gas from the chemistry module to the collection bag is a constant nitrogen purge. The nitrogen gas flows at a rate between 15 - 250 standard cubic centimeters per minute (sccm) from the reaction vessel of the chemistry module through the waste and charcoal filter (in the chemistry module) into the collection bag. The estimated volume for one cleaning cycle and one FDG synthesis is approximately 20-22 L. The AV-45 compound is manufactured on a module that is designed for two syntheses with a total expected nitrogen purge volume of 40-44 L.

B. The size of the ^{18}F gas collection bag for each chemistry module is 100 L. The FDG chemistry module is designed for 4 runs, which would lead to approximately 80-88 L of nitrogen. The chemistry module only discharges gas during synthesis and ceases upon completion of the production run, so the generated volume of gas can be contained within the 100 L bag. While the module may produce 4

PETNET Solutions, Inc.
A Siemens Company

810 Innovation Drive
Knoxville, TN 37932

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

synthesis runs in one production day, the routine production at the St Louis facility is 2 - 3 runs. This provides ample room in the collection system to collect the expected effluent.

The size of the AV-45 gas collection bag for each chemistry module is 80 L. The AV-45 chemistry module is designed for 2 runs, which would lead to approximately 40-44 L of nitrogen. The chemistry module only discharges gas during synthesis and ceases upon completion of the production run, so the generated volume of gas can be contained within the 80 L bag. While the module may produce 2 syntheses in one production day, the routine production at the St. Louis facility is 1 run. This provides ample room in the collection system to collect the expected effluent.

Concern 2

Describe the exposure rate near the hot cell housing the collection bag, and the estimated accumulated dose for an individual working near the hot cell.

Response 2

The exposure rate on the exterior wall of the hot cell, as measured on Monday February 3, 2014, was 0.15 mR/hr after the collection of two FDG production runs. Qualified personnel working on the adjacent hot cell will typically work an average of 1 hour during a full workload of 2 FDG runs and 2 Amyvid runs. The exposure rate emitting solely from the collection bags inside of the hot cell does not result in additional exposure over the background level.

Concern 3

Describe the method used to release the F-18 gas from the collection bag to the stack exhaust system.

Response 3

The bag will be vented to atmosphere after a minimum of 5 half-lives from the last collection. However typical decay time is 8-9 half-lives. Venting will be accomplished either manually or with a vacuum pump.

Concern 4

Provide the method used to determine the radioactivity and the concentration of effluent released, and include the detector calibration and detection sensitivity (µCi/ml).

A. Provide the method and frequency of detector calibration using $^{11}CO_2$ or other positron-emitting gas.

B. Since Cs-137 is used as a calibration check source, please derive the effluent concentration conversion factor based on the monitor response to the Cs-137 check source.

Response 4

A. While calibration using $^{11}CO_2$ is ideal, very few commercial PET radiopharmaceutical manufacturing facilities have the capability to produce ^{11}C. The vast majority of ^{11}C is produced in or for R&D laboratories as there is limited clinical use. Installing the capability to produce ^{11}C is costly and not undertaken solely to produce a calibration gas. Instead PETNET relies on data submitted by the manufacturer that utilizes a set of calibrated releases of ^{15}O and the use of a transfer ^{137}Cs source as outlined in the Lab Impex document included in Attachment A. While not as ideal as a calibrated gaseous release at each site, it provides a level of assurance commensurate to the hazard produced that the activity calculations are reasonably accurate. PETNET has extensively investigated the production of various ^{18}F and ^{13}N gaseous compounds and has successfully used ^{18}F labeled fluoromethane as a calibration gas. However it is not possible to produce ^{18}F-fluoromethane in the chemistry modules available at St. Louis.

B. Please see Attachment A along with the Lab Impex Effluent Concentration Conversion Factor Procedure and the site's most recent data worksheets provided as Attachment B.

Concern 5

Describe how you will be able to identify and control an unexpected leak of F-18 into worker spaces or the environment during the transfer of F-18 to or from the collection bag.

Response 5

Manufacturing personnel will verify and log the connection of the collection system to the chemistry modules at the beginning of each production day. Manufacturing personnel will monitor the stack monitor effluent and document any releases. As soon as conditions are ALARA, the chemistry module and collection bag system will be inspected to determine what caused the leak. PETNET's calculations show that the site could incur up to 1238 bag failures prior to exceeding the Constraint Limit of 10 mrem/year. These calculations are included for your review as Attachment C.

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

Concern 6

Please state whether or not the effluent exhaust/filtration system has been modified as a result of installation of the gas collection bag. If it has, please describe the modified system and provide justification for the modifications.

Response 6

The effluent exhaust/filtration system has not been modified as a result of installation of the gas collection bag.

Concern 7

Describe the alarm set point that will be established for daily effluent releases of F-18 (mCi/day) after installation of the collection bag system. Please provide the basis for establishing the alarm set point.

Response 7

PETNET has reviewed the available data from the Lab Impex Stack Monitoring System and has performed expected public dose calculations to determine an alarm set point. Calculations are provided for your review as Attachment C and they indicate that the public dose per effluent release is 0.0081 mrem. Due to the minimal expected exposure, PETNET will set the ALARA alarm set point at 50,000 µCi (i.e., 4 releases per quarter), which is equivalent to 2.33 mrem.

PETNET is committed to capturing as much of the effluent from the chemistry modules as possible to maintain public radiation exposures ALARA. 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, Cyclotrons and Sources)
810 Innovation Drive
Knoxville, TN 37932
(865) 308-3887 mobile
(865) 218-6355 office
april.chance@siemens.com

Attachments

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

ATTACHMENT A

PG-10 Positron Gas Detector Calibration Data
and Check Source Comparison

Note: This document was sent via e-mail to Kevin Null.

PG-10 Positron Gas Detector Calibration Data and Check Source Comparison

Document Reference: W0215-TD007

LIS DOCUMENT CONTROL RECORD

Title	PG-10 Positron Gas Detector Calibration Data and Check Source Comparison		
Ref	W0215-TD007	Issue	1

Amend #	AMENDMENT RECORD AND DETAILS
0	First issue
1	
2	
3	
4	
5	
6	
7	
8	
9	

Amendment		0	1	2	3	4
PREPARED	BY	J. Parkin				
	DATE	21-03-2013				
CHECKED	BY (Name & Signature)	-				
	DATE	-				
APPROVED	BY (Name & Signature)	-				
	DATE	-				

Amendment		5	6	7	8	9
PREPARED	BY					
	DATE					
CHECKED	BY (Name & Signature)					
	DATE					
APPROVED	BY (Name & Signature)					
	DATE					

COPYRIGHT

Contents

1 Introduction

This report details the development of a calibration method for an installed array of PG-10 positron gas detectors using traceable gas activity concentrations. This method is then related to detector response to a reference ^{137}Cs gamma source that can be placed external to the chamber for detector setup and confirmation of calibration on future systems, effectively providing a secondary calibration method to this original work. The work was carried out with the technical input of the Wolfson Molecular Imaging Centre (WMIC) at the University of Manchester. The purpose of this report is to relate the original calibration data to the gamma reference source so that future systems need not be calibrated in such a manner, reducing the requirement for handling and manipulation of potentially high activities of radioactive material.

1.1 Lab Impex Detectors

Each detector is made up of a cylindrical chamber of radius ~50mm and height ~100mm. Inside this chamber is a light guide of approximate width and height of 13mm and 76mm respectively. The light guide is covered by a cuboidal organic plastic scintillator that is thin in order to minimise background (the thickness of the scintillator is proprietary information). The light guide is then connected to a photomultiplier tube (PMT). Figure 1 shows a schematic diagram of this setup.

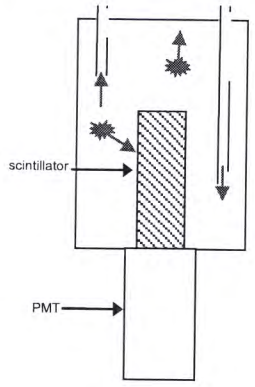


Figure 1: A schematic representation of a Lab Impex PG-10 detector. The gas is drawn in through the right hand tube and out through the other tube; the flow is represented by the blue arrows. Radioisotopes emit β+ particles in all directions as indicated in red. When a β+ particle (positron) collides with the scintillator photons are emitted. These photons are directed into the photomultiplier tube (PMT) by a light guide. The PMT then outputs a voltage of between 0V and 3V to the system

As shown in Figure 1, air is pumped through the detector. As radioisotopes decay in the chamber, the emitted positrons enter the scintillator where they deposit their kinetic energy, primarily by excitation of π-electrons into excited states. These states rapidly decay, emitting a photon.

The light guide is connected to a photomultiplier tube which amplifies the signal from the collected photons.

2 Calibration and Characterisation of PG-10 Detectors

2.1 Closed Loop Calibration of PG-10 Detectors

The Lab Impex systems PG-10 detectors require calibrating so that the raw counts per second (CPS) can be converted into a meaningful activity density (Bq/m^3). This is then used to calculate emissions by multiplying the result up by the measured stack flow.

In order to directly calibrate the detectors a closed loop was used so a known quantity of radioactivity could be circulated for a sustained period of time. This closed loop consists of a gas pump and a five litre container as shown in Figure 2.

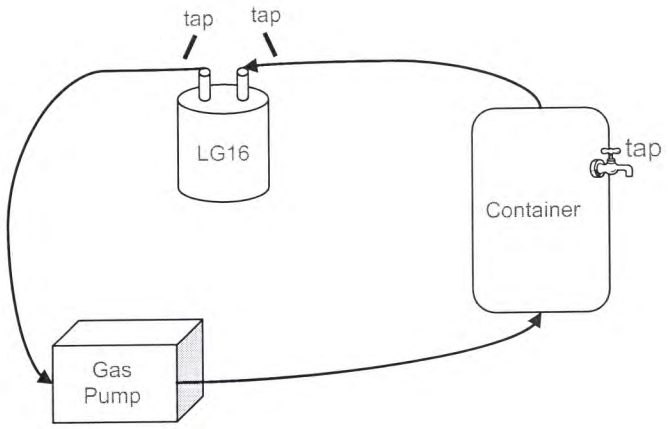


Figure 2: A schematic diagram of the closed loop system. Gas flow is in the direction indicated by the arrows. There is a small tap for connecting a syringe to the container, and taps either side of the pump for blocking air flow.

The basic method used for calibrating the detector using this closed-loop is as follows. A sample of a radioisotope (^{11}C or ^{15}O) is injected via the tap. The pump is then switched on and left running in order for the gas to become completely mixed, so when an aliquot is taken it is representative of the gas in the detector. The decay of the sample in the aliquot is then measured in a separate detector. An accurate quantisation and decay of the aliquot can be compared to the decay of the closed loop as recorded by the Lab Impex detector, and a calibration derived.

2.2 Calibration of BGO for a 10 ml Syringe

The activity that must be accurately measured in the aliquot is low due to the high sensitivity of the PG-10 detector. A maximum activity of approximately 0.5 MBq (approximately 650 MBq/m^3) is observable in the PG-10 detector. Given that the closed loop used has a volume of approximately 7 litres, an aliquot taken in a 10 ml syringe will therefore have a maximum activity

of around 6 kBq. This low level of activity cannot be measured in an ion chamber based dose calibrator. Hence, a more sensitive BGO well detector was used for these calibrations.

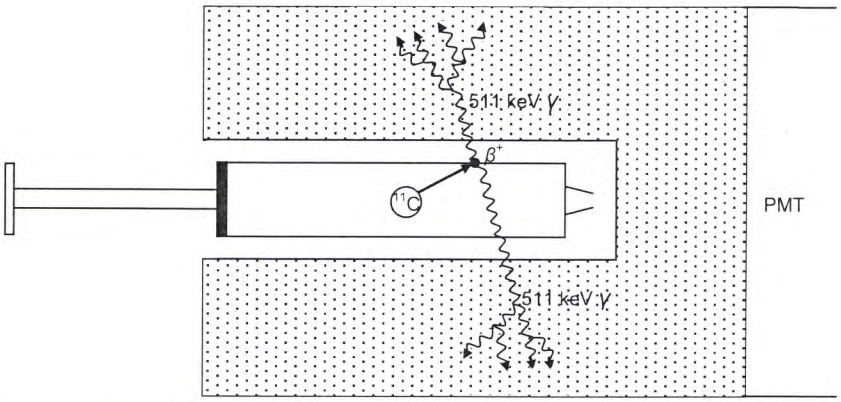


Figure 3: Schematic diagram of a BGO well detector. A syringe containing a gaseous radioisotope, for example 11CO2, is placed in the well. Positrons annihilate with the surface of the syringe, producing back-to-back photons with energy 511keV. These photons enter the BGO crystal where an electromagnetic shower is created. These photons are transmitted to the photomultiplier tube where the signal is amplified. A count is registered if a summation peak of 1022keV is detected. This minimises effects from natural background.

As shown in Figure 3, the BGO is a Bismuth Germanate scintillation detector that works by counting the back-to-back γ-rays emitted by a β^+-particle annihilating with an atomic electron in the reaction

$$e^+e^- \rightarrow 2\gamma \qquad \textbf{[Eq. 1]}$$

where the two photons produced have equal and opposite momentum and energy 511 keV[1, 2].

Accurate reading of the activity in the syringe can be taken due to the low background in the lead shielded BGO detector.

In order to calibrate the BGO to this geometry, the decay of a 10 ml syringe filled with ^{11}C gas was first observed in an ion chamber dose calibrator. This ion chamber is used in the WMIC for measuring radioactive doses to be dispensed for patient PET studies, and is calibrated with a secondary standard source traceable to the UK National Physical Laboratory primary standard.

When a low enough level of activity was reached for recording in the BGO without a significant amount of dead-time (~1kBq) the syringe was transferred to the BGO and the decay recorded over time. The corresponding data from the ion chamber and the BGO is shown in Figure 4.

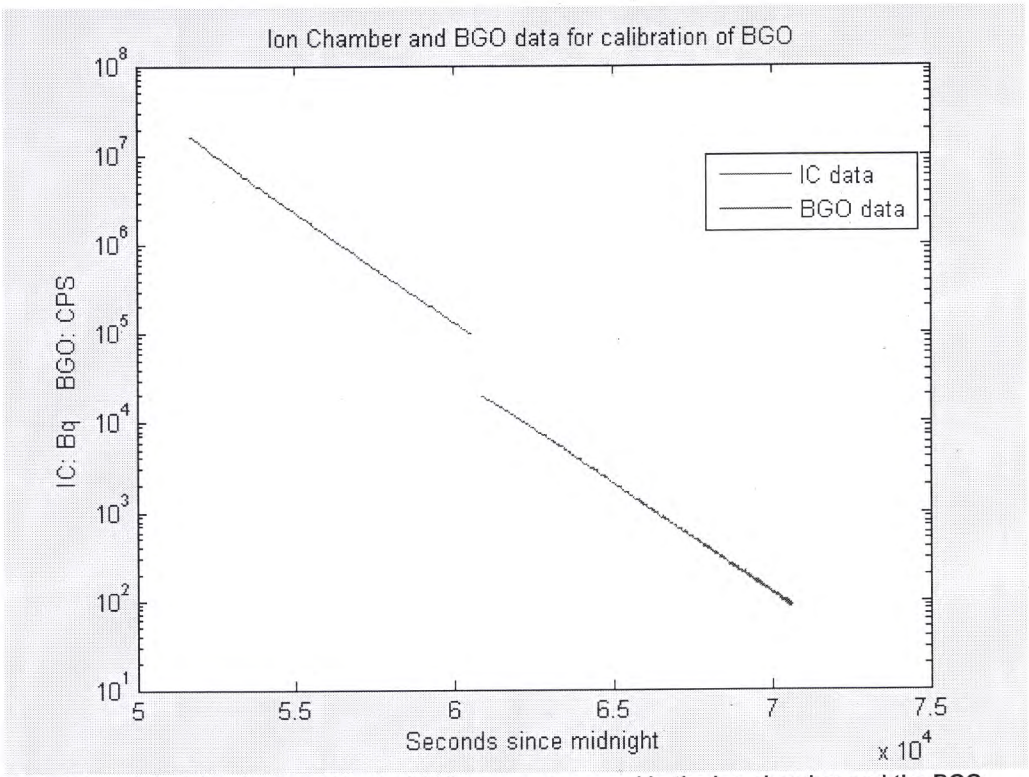


Figure 4: A log plot of the decay of 10 ml of 11C gas as measured in the ion chamber and the BGO

The samples decay according to the equation[3]

$$A(t) = A_0 e^{-\frac{\ln(2)}{\tau}t} \qquad \textbf{[Eq. 2]}$$

where $A(t)$ is the activity of the sample at time t, τ is the half-life of the radioisotope (in the case of ^{11}C this is 1221s[4]) and A_0 is the activity of the sample at t = 0.

A program written in MATLAB was used to allow accurate and efficient analysis of the data. It separately presents both decays graphically and allows the selection of regions of interest (ROI) by the user. The user can choose the ROIs that seem unaffected by dead-time and background noise. The program then fits Equation 2 to the selected data using a library file of an algorithm by Lawson and Hanson[5]. This constrains the fit to the isotopes present without giving negative abundances. A bootstrap re-sampling method is used to calculate the final fitting parameters associated errors. Once the fits are calculated they are compared over a similar region in time resulting in a calibration factor for that detector.

This calibration was repeated three times using ^{11}C and once using ^{15}O. By combining the results of these separate calibrations using a weighted mean a calibration factor for the BGO of 3.71 ± 0.02 was obtained, i.e. for an activity of 3.71Bq the BGO counts one count per second.

This equates to an efficiency of $(100/3.71)\% = 27.0\%$ for this 10ml syringe (SN: 302188) in the BGO detector. This modest efficiency for a large BGO detector is due to the source's extended geometry.

2.3 Closed Loop Calibration of Lab Impex Detectors

2.3.1 *Establishment of a Method for Calibration*

The method for calibrating the detectors was tested originally on a single detector (referenced as LG16 here) during a research project. The closed loop was connected to LG16 as detailed in Figure 2. The detector was shielded from the pump and container as much as possible. A 10 ml syringe of radioactive gas was injected via the tap and mixing occurred over the next 10 minutes. The pump was turned off and the taps either side of the detector closed. An aliquot was then taken from the other side of the taps from the detector. This was to ensure that the gas contained in the detector was not affected by the removal of the aliquot. The decays of the sample and the gas contained in LG16 were observed and logged. The sample decay was automatically logged by software in the BGO, and the decay in LG16 was logged manually from the Lab Impex CMS display.

This closed loop calibration for LG16 was performed twice with ^{11}C (CO_2) and once with ^{15}O (O_2).

The MATLAB analysis program was used to fit Equation 2 to ROIs selected by the user in both the BGO and Lab Impex detectors, as with the calibration of the BGO to the ion chamber. As the detector has known volume 744ml and the BGO has previously been calibrated, the coefficient κ can be calculated from the equation

$$\kappa = \frac{A_0^{BGO}}{C_0^{LI}} \cdot \frac{V^{LI}}{V^{BGO}} \qquad \textbf{[Eq. 3]}$$

where A_0^x, C_0^x and V^x are the activity and CPS at time t = 0, and volume of detector *x*, respectively. This coefficient is related to the efficiency of the detector by the equation

$$eff = \frac{1}{\kappa} \qquad \textbf{[Eq. 4]}$$

The calibration factor for the detector, *K*, can then be calculated using

$$K = \frac{1}{eff * V^{LI}} \qquad \textbf{[Eq. 5]}$$

and strictly speaking has units of volume^{-1} due to the fact that the units of Bq (s^{-1}) and cps (also s^{-1}) cancel. This may be more conveniently thought of for the purposes of this calibration as having units of Bq/litre per cps, or kBq/m^3 per cps. This calibration factor relates the activity in the detector, A^{LI}, to the CPS, C^{LI} via the equation

$$A^{LI} = KC^{LI} \times V^{LI} \qquad \textbf{[Eq. 6]}$$

where V^{LI} is the volume of the chamber of the PG-10 detector. The conclusions then drawn were that this method of calibration and data analysis were appropriate. However, due to the necessity of manually logging the data it was not possible to collect sufficient amounts of data to precisely calibrate the detectors, especially when attempting to calibrate more than one detector.

Following proof of concept, the Lab Impex 9205 automatic data-logging program was used to perform the data acquisition for the calibration of a bank of detectors and the subsequent relation of response to a reference check source.

2.3.2 *Bank Calibration of the Detectors*

In order to practically calibrate a larger number of detectors (in this case 14 in total), it was necessary to calibrate several detectors simultaneously. This was initially tested with a bank of 4 detectors (here referenced as LG16, LG12, G07, G12).

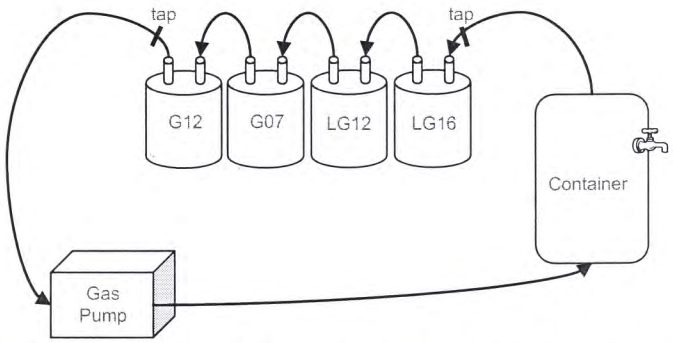


Figure 5: Schematic diagram of the closed-loop system connected to four PG-10 detectors. Gas flow is in the direction indicated by the arrows. There is a small tap for connecting a syringe to the container, and clamps either side of the pump for blocking air flow

The four detectors were connected to the closed loop system as detailed in Figure 5. The method for calibration was repeated as detailed previously, except that after the sample being observed in the BGO had been decaying for twenty minutes a second sample was taken and replaced the first in the BGO. This was in order to check that the gas in the closed-loop system was sufficiently mixed. As the volume of the system had been increased due to the addition of three more detectors it is possible that more time would be required for the gas to mix.

The calibration of this first bank of detectors was repeated twice using $^{11}CO_2$ gas.

Table 1: Summarised results of the calibrations of the first bank of detectors. The error shown on the calibration factor only includes the statistical error from fitting the decay curves to the data from the BGO and PG-10 detectors.

Detector	28 Feb (BGO sample 2)		7 Mar (BGO sample 1 & 2 combined)	
	Calibration Factor, K *(kBq/m^3 per cps)*	Efficiency (%)	Calibration Factor, *K (kBq/m^3 per cps)*	Efficiency (%)
LG16	9.97 ± 0.03	13.3	8.35 ± 0.02	16.0
LG12	7.67 ± 0.02	17.3	8.31 ± 0.02	16.0
G07	8.36 ± 0.02	16.0	8.94 ± 0.03	14.9
G12	8.07 ± 0.02	16.5	8.85 ± 0.02	15.1

Table 1 shows the summarised results of the calibration of the first bank of detectors. The efficiencies of the detectors measured here are similar to those predicted by Monte Carlo models of the detector geometry. This indicates that the method of calibration is appropriate.

It was found that the results from the two BGO samples on the 7th March were consistent, but those on the 28th February disagreed with one another. Since the second sample on 28th February agrees with both samples from 7th March it is probable that this can be explained by the extra time given on the 7th March for the gas to mix before the first sample was taken. For this reason the results from the first sample on 28th February were discarded, and a longer time (~20 minutes) was given for the gas to mix in future experiments.

As all of the detectors were found to have consistent and reproducible calibration factors, the experiment was then extended to connect all 14 detectors together in a single bank to calibrate them all simultaneously. It appears that connecting several detectors together for simultaneous calibration presented no problems to this method of calibration, except for the necessity of longer mixing time.

This calibration of the full bank of 14 detectors was repeated twice using the same method as with the initial bank of four detectors, using $^{11}CO_2$ gas.

Table 2: Empirical efficiencies from the calibrations of all PG-10 detectors using the closed-loop method. The calibration was performed twice with the full bank of detectors using $^{11}CO_2$ gas.

Detector	Efficiency	
	Run1	Run2
LG16	15.7	15.4
LG12	15.7	15.7
G07	15.0	14.4
G12	15.6	12.6
LG08	15.5	15.6
LG10	16.9	16.9
LG17	16.9	16.6
LG11	15.1	15.1
EF14	14.8	14.6
EF17	17.2	17.2
EF15	15.9	13.3
EF06	14.7	13.7
EF16	16.8	13.0
EF12	16.9	13.0

Table 2 shows the empirical efficiencies obtained from the closed-loop calibrations of the detectors. Similarly to the calibration of the first bank of detectors, two BGO samples were taken during each experiment. Again, the first BGO sample from the first experiment was discarded following analysis of the results, as still greater time was required for mixing. This was apparent from comparison with the calibration results already found for detectors LG16, LG12, G07 and G12.

Table 3: Summarised results of the calibrations of all Lab Impex detectors. The error shown on the calibration factor only includes the statistical error from fitting the decay curves to the data from the BGO and LI detectors. The New CMS Factor is the new calibration which would be stored in the CMS for each detector. The full bank of 14 detectors was calibrated twice producing a total of 4 possible BGO samples.

Detector	*Calibration Factor from Bank Calibrations (kBq/m^3 per cps)*	*New CMS Factor (kBq/m^3 per cps)*	*Efficiency (%)*	*Total Number of BGO Samples Used*
LG16	8.86 ± 0.03	8.9	14.9	6
LG12	8.24 ± 0.01	8.2	16.1	6
G07	8.74 ± 0.01	8.7	15.2	6
G12	8.49 ± 0.01	8.5	15.7	6
LG08	8.58 ± 0.02	8.6	15.6	3
LG10	7.91 ± 0.02	7.9	16.8	3
LG17	8.00 ± 0.02	8.0	16.7	3
LG11	8.82 ± 0.02	8.8	15.2	3
EF14	9.06 ± 0.02	9.1	14.7	3
EF17	7.74 ± 0.02	7.7	17.2	3
EF15	9.19 ± 0.02	9.2	14.5	3
EF06	9.40 ± 0.02	9.4	14.1	3
EF16	8.65 ± 0.02	8.7	15.5	3
EF12	8.68 ± 0.02	8.7	15.3	3

The combined results from all calibrations are summarised in Table 3, including the calibration factor, efficiency and the number of samples used for the calibration in each detector.

3 Referencing Calibration Results to ^{137}Cs Check Source Response

The work, having proven the method of calibration and the detector efficiency to be largely uniform across the sample taken, was then extended to correlate the gamma response to the conversion factor.
PG-10 detector LG12, was re-calibrated to prove stability of the calibration method and to take a reference conversion factor against the check source. The method for calibration has been discussed above and is summarised as follows:

- A gaseous radioisotope ($^{11}CO_2$) is injected into the closed-loop system and is circulated by a pump until mixed
- A sample of the gas is then taken and measured in the highly sensitive bismuth germinate (BGO) scintillation detector
- The decays of the BGO sample and the gas in the closed-loop are observed and compared, and a calibration factor inferred

Three samples were taken after different mixing times, in order to ensure that the gas in the closed-loop was sufficiently mixed. As the detector has known volume ~750ml and the BGO has previously been calibrated as per equations 3 to 6. The results are displayed in the table below.

Table 4: Calibration factor and efficiency results from re-calibration of LG12

	Sample 1		Sample 2		Sample 3	
	Calibration Factor ***(kBq/m³ per cps)***	**Efficiency (%)**	**Calibration Factor** ***(kBq/m³ per cps)***	**Efficiency (%)**	**Calibration Factor** ***(kBq/m³ per cps)***	**Efficiency (%)**
LG12	8.2 ±0.2	16.4±0.4	7.8 ± 0.1	17.2 ± 0.2	7.9 ± 0.1	17 ± 0.2

Detector LG12 had previously been found to have a calibration factor of 8.2 kBq/m^3 per cps, providing a secondary confirmation for the calibration of the panel detector. The results from this experiment give a calibration factor of (7.9 ± 0.1) kBq/m^3 per cps.

All detector gas calibration values were then compared to the count rate obtained when a ^{137}Cs check source (LIS Source reference 37) was placed on the detector in the check source position on the top of the gas chamber. Knowing the background corrected count rate response of detector LG12 and the actual gas calibration, a conversion factor could then be calculated, referenced back to the positron gas response and the ^{137}Cs check source response of detector LG12.

In this case, the detector gave a net count rate response of 237.7 cps with the check source and had a calibration factor of 7.9. The calibration factors for all other detectors were then calculated assuming a linear relationship between gamma response and positron gas response. This meant carrying out calculations using the following equation:

$$Source\ Check\ Cal\ Factor\left(\frac{\frac{kBq}{m^3}}{cps}\right)=\frac{237.7}{x}\times 7.9$$

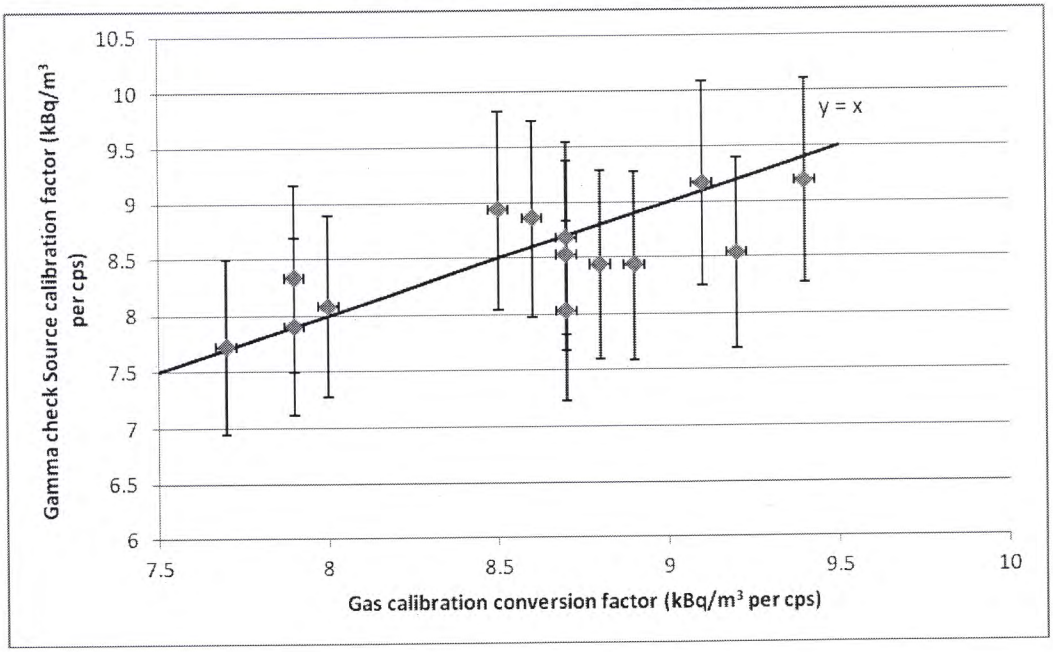
[Eq. 7]

Where x is the PG-10 detector's background corrected count rate with the ^{137}Cs source present. This yields the calibration factors in the table below. The source check calibration factors are compared to the true gas calibration factors. The error from the gas calibration is also reported, as a percentage of the true calibration value. In this case the gas calibration result is assumed to be the true value.

Table 5: Gamma calibration results cross-referenced to gas calibration results

Detector	Background corrected PG-10 source cps	Gas calibration factor (kBq/m^3 per cps)	Source check cal factor (kBq/m^3 per cps)	Error from gas cal (%)
LG16	222.65	8.86 ± 0.03	8.43	-4.81
LG12	237.69	7.9 ± 0.1	7.90	0.00
G07	216.35	8.74 ± 0.01	8.68	-0.69
G12	210.08	8.49 ± 0.01	8.94	5.28
LG08	212	8.58 ± 0.02	8.86	3.24
LG10	225.29	7.91 ± 0.02	8.34	5.38
LG17	232.26	8.00 ± 0.02	8.09	1.06
LG11	222.55	8.82 ± 0.02	8.44	-4.33
EF14	204.75	9.06 ± 0.02	9.17	1.23
EF17	243.19	7.74 ± 0.02	7.72	-0.24
EF15	219.89	9.19 ± 0.02	8.54	-7.07
EF06	204.3	9.40 ± 0.02	9.19	-2.22
EF16	220.28	8.65 ± 0.02	8.52	-1.45
EF12	233.9	8.68 ± 0.02	8.03	-7.51

Table 6: Gas calibration factor plotted against source check calibration factor. Error bars in the y-axis are 10% of reading, error bars in the x axis correspond to the reported error in the gas calibration reading



4 Conclusion

Figure 6 displays the gas calibration result plotted against the check source calibration factor for each of the detectors. A tolerance of ±10 % is assumed for the calibration, and although there is a large spread on the data all points sit within the ±10 % tolerance of the y = x line plotted on the graph. This provides further indication that the check source method will provide an accurate calibration of the detector.

For a more general calibration with a ^{137}Cs check source, the equation in the previous section can be generalised to take into account the activity of a different activity source, or the decay of LIS source 37.

To calculate an appropriate calibration factor (C.F.) with a known activity, A (in Bq), ^{137}Cs check source, the following equation should be used: Therefore, assuming a ^{137}Cs point source in the activity range 100 kBq to 1 MBq is used and it is placed on the centre of the top of the gas chamber in between the inlet and outlet pipes, a conversion factor can be calculated.

$$C.F.\left(\frac{\frac{kBq}{m^3}}{cps}\right) = \frac{237.7}{x} \times 7.9 \times \frac{A}{302540}$$

[Eq. 8]

Where x is the background compensated check source count rate from the PG-10.

This has been shown to yield a conversion factor within ±10% of the true gas calibration value for all detectors calibrated here.

4.1 Factory Calibration

All detectors supplied by Lab Impex Systems are calibrated before supply. This is carried out by first of all setting an appropriate gain and bias voltage defined by the results of a plateau plot using the supplied amplification electronics. They are then calibrated using LIS source 37 according to the ^{137}Cs source check described above. The same source is used to ensure the most accurate correlation possible to the results presented in this report, referencing the performance back to the original gas calibration data. For this calibration, the net count rate, x (source count rate minus background count rate), is recorded and entered into equation 8, along with the activity of LIS source 37, once decay corrections have been made for the activity of the check source on the date of calibration of the PG-10.
The plateau plot, amplifier and bias setting as well as the conversion factor are recorded for future reference, before the new conversion factor is entered into the CMS parameters. This provides confidence of the proper operation and accuracy of the detector results.

Appendix A: Final gas calibration details

Equipment List

Detector LG12
Detector serial number: B0245/020
CMS Model number: CMS 1L/4
CMS serial number: B0250/13

BGO well chamber part number. Scionix detector 80 BP 90 / 3.5M-BGO-X
Serial number: SAH504.

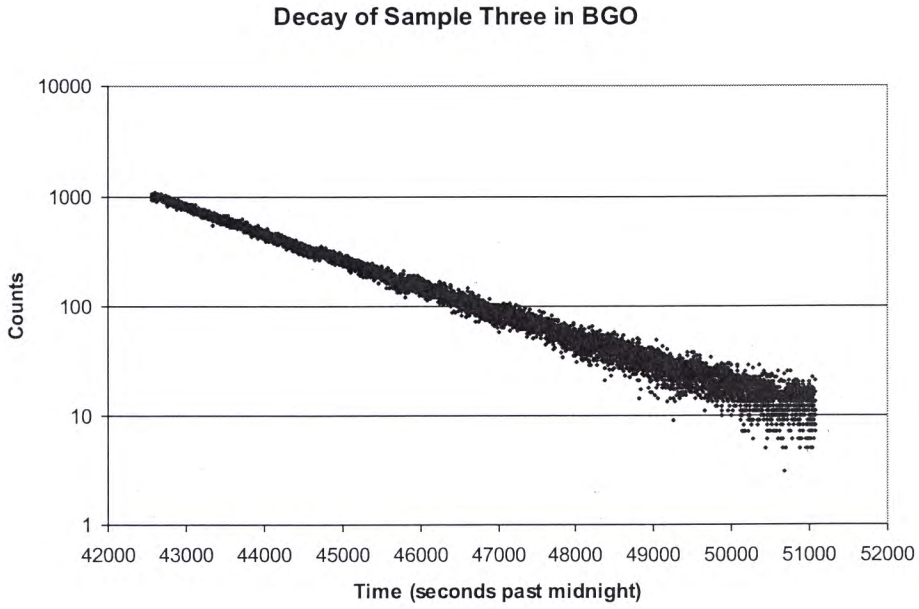
- Photomultiplier base and pre-amp (Ortec Model 296).
- A Minibin and power supply (Ortec Model 4006).
- A shape amplifier with timing SCA (Ortec Model 590A).
- Delay electronics (Ortec Model 427A).
- A data logger (Measurement Computing - PMD-1208LS).

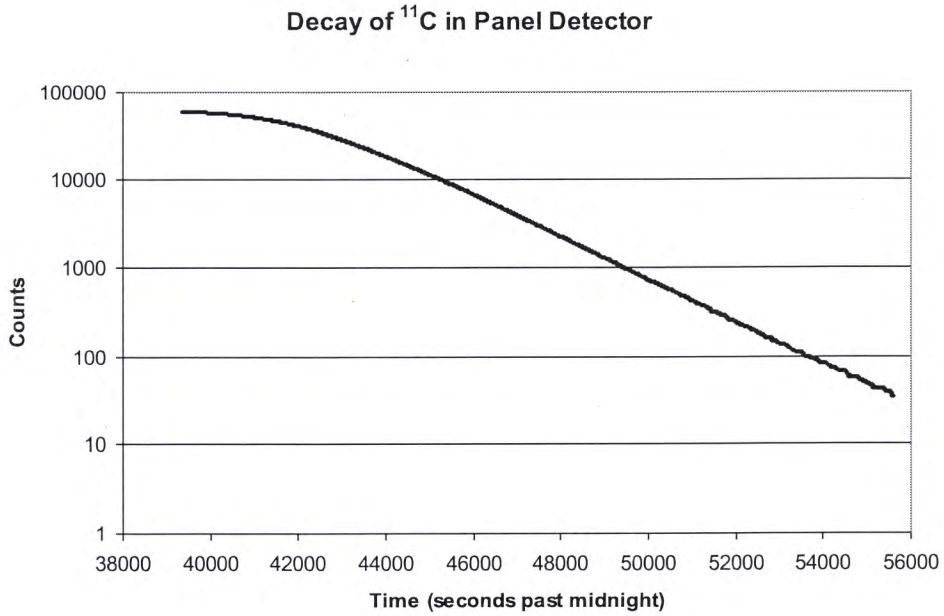
Calibration date: February, 2006
Calibrated by: Neil Hughes
Niall Robinson

Dose Calibrator Model: Isomed 2000
Calibration: yearly against NPL/NWMP
Calibration: Michael Green
Calibration checks: weekly against check source

Test Performed at: Wolfson Molecular Imaging Centre
The University of Manchester
27 Palatine Road
Withington
Manchester
M20 3LJ
Test date: 6th June 2006
Test performed by Neil Hughes
Niall Robinson

Example Data





ATTACHMENT B

PG-10 Cs-137 Calibration Check and Data Worksheets

Note: These documents were sent via e-mail to Kevin Null.

LIS DOCUMENT CONTROL RECORD

TITLE: PG-10 Cs-137 Calibration Check

ISSUE: 1.0

Amendment No.	AMENDMENT RECORD AND DETAILS
0	New Issue
1	To provide tolerance statement
2	
3	
4	
5	
6	
7	
8	
9	

Amendment		**0**	**1**	**2**	**3**	**4**
PREPARED	BY	NC	NC			
	DATE	05/10/08	18/8/09			
APPROVED	BY	JR	JR			
	DATE	05/10/08	18/8/09			
Amendment		**5**	**6**	**7**	**8**	**9**
PREPARED	BY					
	DATE					
APPROVED	BY					
	DATE					

INTRODUCTION

A $^{11}CO_2$ Gas Calibration at WMIC gave the following correlation between detector gas response and the response to a Cs137 check source. (see Annex A)

Gamma Source Strength	PG-10 Count Rate (Background subtracted)	Source Activity to Count Rate Ratio	Equivalent Conversion Factor
8176757 pCi	237.7 cps	34397 pCi per cps	0.213 pCi/ml per cps

CS-137 CALIBRATION CHECK

The PG-10 can be calibrated on-site using a Cs137 check source using the the following calculation

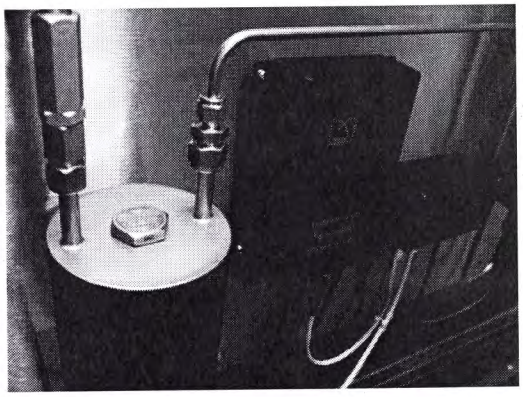
NEW CONVERSION FACTOR = (Site Source (pCi) / 34397) * (1 / X) * 0.213

Where X = the background subtracted source count-rate

PROCEDURE

1.1 With no source present, record the background cps count-rate

1.2 Place the Cs-137 check source on the outside of the PG-10 chamber, as detailed in the photograph below, and record cps count-rate



Lab Impex Systems	LIS Job No:	Customer Ref:

PG-10
CERTIFICATE OF CALIBRATION TESTS

INSTRUMENT

Serial No.	Channel
Type	Description

SOURCE.

Ref. No. _____
Isotope. _____
Half Life Corrected Activity _____pCi (A1)

BACKGROUND TEST

Background
(no source present)

_____cps (A2)

SOURCE TEST

Source
in position

_____cps (A3)

CONVERSION FACTOR CALCULATION

Conversion Factor = **(A1** / 34397) * (1 / **A3-A2**) * 0.213 =_____

If the new calculated conversion factor is within +/- 10% of the existing conversion factor, LIS advise the existing conversion factor is retained and no adjustment is made.

Note: It is the obligation of the client to gain approval for the acceptability of this calibration method from local radiation protection staff and the site regulator and LIS take no liability in this regard.

Completed By:-		**Date:**	

ANNEX A: CALIBRATION OF PG-10 GAS DETECTOR

Method

The panel detector connected in series to previously calibrated detector LG12 via a closed-loop system. The method for calibration has been established previously with this model of detector and is as follows:

- A gaseous radioisotope ($^{11}CO_2$) is injected into the closed-loop system and is circulated by a pump until mixed
- A sample of the gas is then taken and measured in the highly sensitive bismuth germinate (BGO) scintillation detector
- The decays of the BGO sample and the gas in the closed-loop are observed and compared, and a calibration factor inferred

Three samples were taken after different mixing times, in order to ensure that the gas in the closed-loop was sufficiently mixed.

As the detector has known volume ~750ml and the BGO has previously been calibrated (see report Hughes and Robinson, 2006) , the coefficient κ can be calculated from the equation

$$\kappa = \frac{A_0^{BGO}}{C_0^{LI}} \cdot \frac{V^{LI}}{V^{BGO}} \qquad \textbf{[Eq. 1]}$$

where A_0^x, C_0^x and V^x are the activity and CPS at time t = 0, and volume of detector *x*, respectively. This coefficient is related to the efficiency of the detector by the equation

$$eff = \frac{1}{\kappa} \qquad \textbf{[Eq. 2]}$$

The calibration factor for the detector, *K*, can then be calculated using

$$K = \frac{1}{eff * V^{LI}} \qquad \textbf{[Eq. 3]}$$

and has units of activity * volume-1 * cps-1. This calibration factor relates the activity in the detector, A^{LI}, to the CPS, C^{LI} via the equation

$$A^{LI} = KC^{LI} \qquad \textbf{[Eq. 4]}$$

Figure 1
Results

	Sample 1		Sample 2		Sample 3	
	Calibration Factor (l^{-1})	**Efficiency (%)**	**Calibration Factor (l^{-1})**	**Efficiency (%)**	**Calibration Factor (l^{-1})**	**Efficiency (%)**
LG12	8.2 ±0.2	16.4±0.4	7.8 ± 0.1	17.2 ± 0.2	7.9 ± 0.1	17 ± 0.2
Panel Detecto r	7.2 ± 0.2	18.6 ± 0.5	6.8 ± 0.1	19.9 ± 0.2	6.8 ± 0.2	19.7 ± 0.5

Detector LG12 had previously been found to have a calibration factor of 8.2 l^{-1}, providing a secondary confirmation for the calibration of the panel detector. The results from this experiment give a calibration factor of (7.9 ± 0.1)l^{-1}.

Combining the results for the panel detector using a weighted mean gives a calibration factor of (6.8 ± 0.1)l^{-1} and an efficiency of (19.7 ± 0.2)%

Conclusion

The panel detector has a calibration factor of (6.8 ± 0.1)l^{-1} and an efficiency of (19.7 ± 0.2)%

This is confirmed by the close agreement of the calibration factor for LG12 to its previously measured value.

Equipment List

Panel Detector
Detector serial number: B0315/008
CMS Model number: CMS 1L/4
CMS serial number: B0250/12

Detector LG12
Detector serial number: B0245/020
CMS Model number: CMS 1L/4
CMS serial number: B0250/13

BGO well chamber part number. Scionix detector 80 BP 90 / 3.5M-BGO-X
Serial number: SAH504.

- Photomultiplier base and pre-amp (Ortec Model 296).
- A Minibin and power supply (Ortec Model 4006).
- A shape amplifier with timing SCA (Ortec Model 590A).
- Delay electronics (Ortec Model 427A).
- A data logger (Measurement Computing - PMD-1208LS).

Calibration date: February, 2006
Calibrated by: Neil Hughes
Niall Robinson

Dose Calibrator Model: Isomed 2000
Location: G09
Calibration: yearly against NPL/NWMP
Calibration: Michael Green
Calibration checks: weekly against check source

Test Performed at: Wolfson Molecular Imaging Centre
The University of Manchester
27 Palatine Road
Withington
Manchester
M20 3LJ
Test date: 6th June 2006
Test performed by Neil Hughes
Niall Robinson

Cross Reference to Original Results for Detector B0245-020

LIS source no.2, ^{137}Cs, Emission Rate: 302,540 Bq 01/10/03.

Reading obtained = 237.7 cps (background subtracted).

Therefore 237.7cps should give a conversion factor of 7.9

$\frac{237.7}{x} \times 7.9$ will give future detectors conversion factors, where x is the reading obtained using source LIS 2.

The certificate of calibration has been updated accordingly.

Lab Impex Systems	LIS Job No:	Customer Ref:

PG-10
CERTIFICATE OF CALIBRATION TESTS

INSTRUMENT Lab Impex PM 1-1 Pet Monitoring System

Serial No.	B02555/010	Channel	
Type	CMS-1LG	Description	

SOURCE.

Ref. No. IPL
Isotope: Cs-137.
Half Life Corrected Activity 195,060,000 pCi (A1)

BACKGROUND TEST

Background (no source present)

2.47 cps (A2)

SOURCE TEST

Source in position

2970 cps (A3)

CONVERSION FACTOR CALCULATION

Conversion Factor = (A1 / 34397) * (1 / A3-A2) * 0.213 = 0.407

$\frac{195,060,006}{34397} \cdot \frac{1}{2968} \cdot 0.213 = 0.407$

If the new calculated conversion factor is within +/- 10% of the existing conversion factor, LIS advise the existing conversion factor is retained and no adjustment is made.

$0.407 - 0.3929 / 0.407 = 3.5\%$

Note: It is the obligation of the client to gain approval for the acceptability of this calibration method from local radiation protection staff and the site regulator and LIS take no liability in this regard.

Completed By:-	Rita Bull	Date:	4-15-13

Lab Impex Systems	LIS Job No:	Customer Ref:

PG-10
CERTIFICATE OF CALIBRATION TESTS

INSTRUMENT Lab Impex PM1-1 PET Monitoring System

Serial No.	B0255/010	Channel	
Type	CMS-1LG	Description	

SOURCE.

Ref. No. Cs-137
Isotope.
Half Life Corrected Activity 1.91E8 pCi (A1)

BACKGROUND TEST

Background (no source present)

3.00 cps (A2)

SOURCE TEST

Source in position

2950.0 cps (A3)

CONVERSION FACTOR CALCULATION

Conversion Factor = (**A1** / 34397) * (1 / **A3-A2**) * 0.213 = 0.40 pCi/ml per cps

If the new calculated conversion factor is within +/- 10% of the existing conversion factor, LIS advise the existing conversion factor is retained and no adjustment is made.

Note: It is the obligation of the client to gain approval for the acceptability of this calibration method from local radiation protection staff and the site regulator and LIS take no liability in this regard.

Completed By:-	Rani D	Date:	2/7/14

ATTACHMENT C

Public Dose Calculations for Patio Area
using
ICRP/NCRP Guidelines and Universal Assumptions

ICRP/NCRP Guidelines & Assumptions							
1	Reference Man (70 kg) Breathing Rate =			**2.00E+04**	**ml/min**		
2	The Average Effluent Activity at St. Louis =			**173**	**µCi**		
3	Effluent Flow Rate =	**1080**	**ft^3/min =**	**3E+07**	**ml/min**		
4	Time of emission =	**20**	**minutes**				
5	Bkg conc. =	**8.00E-07**	**µCi/ml**				
6	Patio Effluent Concentration =	**2.83E-07**	**µCi/ml**				
7	10 CFR 20 Effluent Limit (50 mrem/yr) =			**1.00E-07**	**µCi/ml**		
8	10 CFR 20 Effluent Constraint Limit (10 mrem/yr) =					**2E-08**	**µCi/ml**
9	10 CFR 20 Effluent ALI for F-18 =	**7E+04**	**µCi**	**=**	**5000**	**mrem**	
10	Concentration Intake Rate =	**6E-03**	**µCi/min**				
11	Intake (Reference Man) =	**0.113**	**µCi**				
12	All gas is captured using Tedlar Bags for each chemistry module						
13	Effluent Releases per year due to system malfunction =			**1**			
14	Per NCRP 123 models; the effluent concentration for any area which is less than 100 meters away is equal to the measured concentration at the measured release point, with no dilution factor.						

Annual Dose to Reference Man in Patio & ALARM Setpoint Criteria		
Activity Intake per Release =	**0.113**	**µCi**
Dose to Reference Man per the Released Patio Effluent Concentration =	**0.0081**	**mrem**
Number of releases needed to reach NRC's Constraint Limit of 10 mrem =	1238	
ALARA Alarm Set Point of 4 releases per quarter (50,000 µCi equiv.) which constitutes a public dose of 2.33 mrem/qtr.		

From: (865) 218-6355
April Chance

810 Innovation Drive

Knoxville, TN 37932

Origin ID: RKWA

FedEx Express

J1410140207030v

Ship Date: 05MAR14
ActWgt: 1.0 LB
CAD: 105091792/INET3490

Delivery Address Bar Code

Ref # St Louis 919
Invoice #
PO #
Dept #

SHIP TO: (630) 329-9854 BILL SENDER

Kevin Null
US Nuclear Regulatory Comm. RIII
2443 WARRENVILLE RD STE 210

LISLE, IL 60532

MON - 10 MAR AA
EXPRESS SAVER

TRK# 0201 7981 1194 0897

60532
IL-US

SE ENLA

ORD

522G1/CC4F/F220

After printing this label:
1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.
Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com.FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery,misdelivery,or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim.Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental,consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss.Maximum for items of extraordinary value is $1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.