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Original Article

การศึกษาประสิทธิภาพการทำงานของเครื่องบริหารสารเภสัชรังสีอัตโนมัติสำหรับผู้ป่วยที่มาตรวจด้วยเครื่องเพท/ซีที ที่โรงพยาบาลจุฬาลงกรณ์

The study of performances of an automated radiopharmaceutical administration for PET/CT patients at King Chulalongkorn Memorial Hospital

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บทคัดย่อ

บทนำ: เครื่องบริหารสารเภสัชรังสีอัตโนมัติสำหรับ ^{18}F-FDG ช่วยลดขั้นตอนการเตรียมสารเภสัชรังสีสำหรับฉีดด้วยมือ โดยมีเครื่องวัดความแรงรังสีอยู่ภายใน ทำให้ลดการได้รับรังสีของผู้ปฏิบัติงานเวชศาสตร์นิวเคลียร์ทั้งนักรังสีการแพทย์และพยาบาลผู้ทำหน้าที่ฉีดยา **วัตถุประสงค์:** ทดสอบประสิทธิภาพเครื่องวัดความแรงรังสีที่อยู่ภายในเครื่องบริหารสารเภสัชรังสีอัตโนมัตินี้ตามกระบวนการควบคุมคุณภาพ และทำการเปรียบเทียบความแรงรังสีที่ได้จากเครื่องบริหารสารเภสัชรังสีอัตโนมัตินี้ว่ามีความแตกต่างจากที่วัดได้จากเครื่องวัดความแรงรังสีที่ใช้งานสำหรับเครื่องเพท/ซีทีหรือไม่ **วิธีการศึกษา:** ใช้ซีเซียม-137 เป็นสารกัมมันตรังสีมาตรฐานในการทดสอบความแม่นยำและความถูกต้องของการวัด ความคงที่ของการวัดซ้ำในแต่ละวัน และใช้ ^{18}F-NaF ในการทดสอบการตอบสนองการวัดโดยใช้ความแรงรังสีเริ่มต้นที่ 40.73 มิลลิคูรี สลายตัวจนเหลือความแรงรังสี 0.1 มิลลิคูรี ว่ามีการอ่านค่าได้อยู่ในแนวเส้นตรงหรือไม่ และเปรียบเทียบค่าความแรงรังสีที่ได้จากเครื่องบริหารสารเภสัชรังสีอัตโนมัตินี้กับเครื่องวัดความแรงรังสีสำหรับเครื่องเพท/ซีทีว่าต่างกันหรือไม่ สถิติที่ใช้ทดสอบคือ Pair t-test ที่ระดับนัยสำคัญ 0.01 **ผลการศึกษา:** เครื่องบริหารสารเภสัชรังสีอัตโนมัติมีความแม่นยำที่ร้อยละ 0.23 ความถูกต้องที่ร้อยละ 0.42 ความคงที่ของการวัดซ้ำในแต่ละวันไม่เกินร้อยละ ±5 มีการตอบสนองความแรงรังสีของ ^{18}F เป็นเส้นตรงได้ค่าครึ่งชีวิตที่ 109.73 นาที ต่างจากค่าจริงร้อยละ 0.009 ความแรงรังสีที่ได้จากเครื่องบริหารสารเภสัชรังสีอัตโนมัติเปรียบเทียบกับเครื่องวัดความแรงรังสีสำหรับเครื่องเพท/ซีที แตกต่างกันอย่างไม่มีนัยสำคัญทางสถิติ (p>0.01) **สรุปผลการศึกษา:** เครื่องวัดความแรงรังสีที่อยู่ภายในเครื่องบริหารสารเภสัชรังสีอัตโนมัตินี้ผ่านการทดสอบการควบคุมคุณภาพ ความแรงรังสีที่ได้ออกมาในช่วง 1-18 มิลลิคูรี ไม่แตกต่างเมื่อเปรียบเทียบกับการวัดด้วยเครื่องวัดความแรงรังสีสำหรับเครื่องเพท/ซีที

คำสำคัญ: เครื่องบริหารสารเภสัชรังสีอัตโนมัติ, ระบบการฉีดยาสำหรับการตรวจเพทซีที

Abstract

Introduction: An automated dispensing and infusion system for ^{18}F-FDG can be simplified the process for manual injection preparation. Since dose calibrator is integrated into the system, this could reduce the radiation exposure to nuclear medicine technologists and nurses who perform injections. **Objective:** This study aimed to test the performance of the integrated dose calibrator of an automated radiopharmaceutical administration based on the dose calibrator quality control procedures. The output activity was compared with that measured by the dose calibrator used for the PET/CT imaging. **Methods:** A standard reference source of ^{137}Cs was used to test the precision and accuracy of measurements and the reproducibility test. ^{18}F-NaF was used to test the linearity of activity response with an initial activity of 40.73 mCi until activity decay to 0.1 mCi. The dose calibrator for PET/CT was used to measure activity output from this automated radiopharmaceutical administration. A paired t-test was used to determine statistically significant at a p-value of 0.01. **Results:** The integrated dose calibrator had a precision of 0.23% and an accuracy of 0.42%. In the test of repeatability, reproducibility of the measurements was within an acceptable limit of ±5%. The straight line fit to the activity response of ^{18}F and physical half-life was calculated using the trend line at 109.73 minutes with the difference of 0.009% from the actual. Activity obtained from this automated radiopharmaceutical administration was compared to the activity measured by dose calibrator for PET/CT, and there was no statistically significant ($p>0.01$). **Conclusion:** The integrated dose calibrator of an automated radiopharmaceutical administration had passed the quality control tests. The injected activity in the range of 1 - 18 mCi was not different when measured with the dose calibrator for PET/CT.

Keywords: Automated administration, PET infusion system

Introduction

King Chulalongkorn Memorial Hospital (KCMH), Thai Red Cross Society, has been providing PET/CT system examinations since 2006. At KCMH, a 15 mCi (millicurie) unit dose of ^{18}F-FDG (^{18}Fluorine-Fluorodeoxy-D-gluclose) was ordered for each patient at the calibration time. According to the radiopharmaceutical activity to be injected into the patient, the activity should be calculated based on the patient's weight at 0.11 mCi/kg[1]. The nuclear medicine technologist then prepared activity of ^{18}F-FDG for injection and verified by measured it with the dose calibrator again before put this ^{18}F-FDG syringe in the PET syringe shield. After that, it was handed over to the nurse to inject into the patient as shown in Figure 1. After injection, the nuclear medicine technologist took the syringe to measure the residual activity and calculated the net activity injected into the patient. In PET/CT examination, an SUV (Standardized Uptake Value) was measured according to Equation 1 [2]. Accuracy of the injected dose was important for diagnostic imaging or monitoring cancer treatment.

$$SUV = \frac{\text{Radioactive concentration in tissue}}{\text{Injected dose /Patient body weight}} \quad (1)$$

Figure 1 (Left) ^{18}F-FDG as a unit dose. (Middle) After the desired activity had been prepared, the ^{18}F-FDG syringe was put in a syringe shield for delivered to the injecting room. (Right) Nurse was injecting ^{18}F-FDG to the patient.

Based on the radiopharmaceutical dose preparation, the nuclear medicine technologist and nurse received high radiation doses. Before the end of 2021, KCMH had provided an automatic radiopharmaceutical injection system for ^{18}F-FDG. ^{18}F-FDG was ordered in multi-dose vials. The requested patient dose may be entered by using a personalized dosing formula or manually. When the nurse connects the patient administration safety (PAS) line from this automated

radiopharmaceutical administration to the intravenous (IV) line of the patient, as shown in Figure 2, the nuclear medicine technologist was performed saline injection test to ensure the radiopharmaceutical did not leak out of the vein or cause blockage. The radiopharmaceutical dose preparation was carried out using a pump motor according to the desired activity and was measured with the integrated dose calibrator. After the nuclear medicine technologist pressed the infuse touch screen tab, the radiopharmaceutical was injected into the patient, and followed by normal saline flush to help that all the radiopharmaceutical in the line made its way into the patient. After that, an injection sticker was printed out showing the injection time and activity. As a result of this process, both nuclear medicine technologists and nurses were exposed to less radiation. In several studies shown that an automated dispensing and infusion system was help reduced radiation exposure to the nuclear medicine workers[3-5]. Therefore, this study aimed to verify the reliability of the automated radiopharmaceutical administration performance. The dose calibrator used for PET/CT was used to compare the activity obtained from this automated radiopharmaceutical administration.

Figure 2 (Left) Nurse connecting the PAS line. (Middle) Nuclear medicine technologist was performed automated ^{18}F-FDG administration through the PAS line. (Right) Screen display the graph of ^{18}F-FDG activity decreased from the integrated dose calibrator.

Materials & Methods

The automated radiopharmaceutical administration system used in this study was the Intego PET infusion system (model Medrad Intego, Bayer Medical Care Inc., Indianola, PA), and the standard radioactive material used in quality control was ^{137}Cs (Cesium-137) with an activity of 0.219 mCi referenced on February 23, 2021, as shown in Figure 3. The precision test of integrated dose calibrator was performed by measured ^{137}Cs 10 times and the results were averaged. The precision of each measurement was calculated using equation 2

$$\text{Precision (\%)} = 100\left(\frac{A_i-\bar{A}}{\bar{A}}\right) \quad (2)$$

where A_i is the measured value at each measurement and $\bar{A}$ is the mean of 10 measurements. The activity of ^{137}Cs is calculated to the day of measurement by using equation 3.

$$C = C_0 e^{-\lambda t} \quad (3)$$

where C is the activity at time t, C_0 is the initial activity, λ is the decay constant ($\ln_2/T_{1/2}$), where ^{137}Cs has half-life ($T_{1/2}$) of 30 years, t is the time from the reference date to the day of measurement. The accuracy of measurement was calculated using Equation 4.

$$\text{Accuracy (\%)} = 100\left(\frac{\bar{A}-C}{C}\right) \quad (4)$$

where C is the calculated activity.

Figure 3. MedRad Intego PET infusion system and ^{137}Cs reference source used in quality control.

^{137}Cs, as the reference source, was measured daily to check the reproducibility of the performance. ^{18}F-NaF (Fluorine-18 Sodium fluoride) was used to test the linearity of activity response. An initial activity of ^{18}F-NaF was 40.73 mCi. The MedRad Intego displayed the measured activity every 10 minutes during the test. The close circuit camera was used to record and playback

display screen every half an hour from the beginning until activity decays to 0.1 mCi, as shown in Figure 4.

Figure 4 (Left) Close circuit camera was used to record screen display. (Middle) Screen display at beginning (Right) Screen display after 6 hours.

The comparison of ^{18}F-FDG activity obtained from an automated radiopharmaceutical administration system with the dose calibrator for PET (model CRC-55tR, Mirion Technologies, Capintec. Inc., NJ). At the beginning, the time of the MedRad Intego to match the CRC-55tR dose calibrator was adjusted. Prescribed ^{18}F-FDG activity from the MedRad Intego values from 1 mCi up to 18 mCi. ^{18}F-FDG obtained from the MedRad Intego was injected into a plastic cup and measured with the CRC-55tR dose calibrator as shown in figure 5.

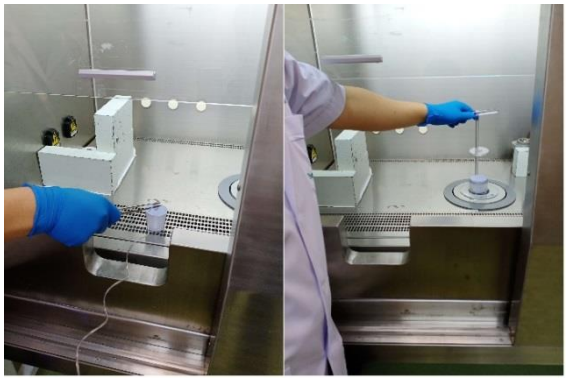

Figure 5 (Left) Shown the injecting output of ^{18}F-FDG from MedRad Intego into a plastic cup (Right) Measurement of ^{18}F-FDG activity in the plastic cup with CRC-55tR dose calibrator.

Results

The activity of ^{137}Cs that was measured 10 times was manipulated to obtain the mean and standard division (SD) results. The percentage different between the individual measured activity and their mean according to equation 2 were shown in table 1 as the precision test.

From table 1, the mean measurement of ^{137}Cs was 0.2145 mCi, measured on March 23, 2022, the expected activity according to equation 3 was 0.2136 mCi. The accuracy of measurement according to equation 4 was 0.42%. For the reproducibility test, ^{137}Cs, a reference source, was measured at the beginning of each day of used. These values were record and plotted against date on a linear graph, as shown in table 2 and figure 6. This study was performed from January to April 2022.

Table 1. The precision (%) of ^{137}Cs measurements from the integrated dose calibrator.

Measured	Reading (mCi)	Precision (%)
1	0.215	0.2331
2	0.215	0.2331
3	0.215	0.2331
4	0.214	-0.2331
5	0.214	-0.2331
6	0.215	0.2331
7	0.214	-0.2331
8	0.215	0.2331
9	0.214	-0.2331
10	0.214	-0.2331
Mean	0.2145	
SD	0.0005	

For linearity test, the measured activity of ^{18}F-NaF was compared with the expected activity. The results are shown in Table 3 and plotted graph between the measured activities against time are shown in Figure 7. The percentage error between measured activity and expected activity are shown in Figure 8.

For comparison test, the activity output from MedRad Intego was measured by the CRC-55tR dose calibrator (with decay correction). The results are shown on table 4, and the relationship between two modalities is shown in figure 9.

Table 2 The daily measurement of ^{137}Cs reference source.

Date	Measured (mCi)	Date	Measured (mCi)	Date	Measured (mCi)	Date	Measured (mCi)
4-Jan-22	0.215	1-Feb-22	0.216	2-Mar-22	0.215	30-Mar-22	0.216
5-Jan-22	0.216	2-Feb-22	0.216	3-Mar-22	0.215	31-Mar-22	0.216
6-Jan-22	0.216	3-Feb-22	0.215	4-Mar-22	0.215	--	--
7-Jan-22	0.216	4-Feb-22	0.216	7-Mar-22	0.216	1-Apr-22	0.215
10-Jan-22	0.216	7-Feb-22	0.215	8-Mar-22	0.216	4-Apr-22	0.215
11-Jan-22	0.216	8-Feb-22	0.215	9-Mar-22	0.215	5-Apr-22	0.216
12-Jan-22	0.216	9-Feb-22	0.216	10-Mar-22	0.216	7-Apr-22	0.215
13-Jan-22	0.216	10-Feb-22	0.216	11-Mar-22	0.214	8-Apr-22	0.215
14-Jan-22	0.216	11-Feb-22	0.215	14-Mar-22	0.216	11-Apr-22	0.216
17-Jan-22	0.216	14-Feb-22	0.215	15-Mar-22	0.215	12-Apr-22	0.215
18-Jan-22	0.216	15-Feb-22	0.216	16-Mar-22	0.215	18-Apr-22	0.214
19-Jan-22	0.216	17-Feb-22	0.216	17-Mar-22	0.216	19-Apr-22	0.215
20-Jan-22	0.216	18-Feb-22	0.216	18-Mar-22	0.215	20-Apr-22	0.214
21-Jan-22	0.216	21-Feb-22	0.215	21-Mar-22	0.215	21-Apr-22	0.214
24-Jan-22	0.216	22-Feb-22	0.215	22-Mar-22	0.214	22-Apr-22	0.214
25-Jan-22	0.216	23-Feb-22	0.215	23-Mar-22	0.215	25-Apr-22	0.214
26-Jan-22	0.216	24-Feb-22	0.215	24-Mar-22	0.215	26-Apr-22	0.214
27-Jan-22	0.216	25-Feb-22	0.216	25-Mar-22	0.215	27-Apr-22	0.215
28-Jan-22	0.216	--	--	28-Mar-22	0.215	28-Apr-22	0.215
31-Jan-22	0.216	1-Mar-22	0.216	29-Mar-22	0.215	29-Apr-22	0.215

Table 3 The activity measured from MedRad Intego compared to the expected activity and the percentage error.

Elapsed time (Hr)	Measured activity (mCi)	Expected activity (mCi)	Error (%)	Elapsed time (Hr)	Measured activity (mCi)	Expected activity) (mci)	Error (%)
0	40.73	40.73	0	8.5	1.62	1.627	-0.411
0.5	33.7	33.701	-0.003	9	1.34	1.346	-0.443
1	27.86	27.885	-0.090	9.5	1.11	1.114	-0.331
1.5	23.07	23.073	-0.012	10	0.92	0.921	-0.162
2	19.08	19.091	-0.058	10.5	0.76	0.762	-0.324
2.5	15.79	15.796	-0.041	11	0.63	0.631	-0.140
3	13.06	13.070	-0.079	11.5	0.52	0.522	-0.385
3.5	10.81	10.815	-0.044	12	0.43	0.432	-0.446
4	8.94	8.948	-0.094	12.5	0.36	0.357	0.732
4.5	7.39	7.404	-0.191	13	0.3	0.296	1.451
5	6.12	6.126	-0.104	13.5	0.24	0.245	-1.912
5.5	5.06	5.069	-0.180	14	0.2	0.202	-1.211
6	4.19	4.194	-0.103	14.5	0.17	0.168	1.484
6.5	3.47	3.470	-0.014	15	0.14	0.139	1.006
7	2.87	2.872	-0.055	15.5	0.12	0.115	4.634
7.5	2.37	2.376	-0.253	15.84	0.1	0.101	-1.068
8	1.96	1.966	-0.304	--	--	--	--

Table 4 The percentage difference between the prescribed activity and the activity output from MedRad Intego, and this output activity compared to the measured activity by CRC-55tR dose calibrator (with decay correction).

Prescribed (mCi)	MedRad (mCi)	Output Error (%)	CRC-55tR (mCi)	Activity Error (%)
1	0.98	-2	0.991	-1.13
2	1.98	-1.00	1.993	-0.63
3	3.01	0.33	3.009	0.04
4	3.98	-0.50	3.975	0.13
5	5.03	0.60	5.042	-0.23
6	6.05	0.83	6.068	-0.30
7	6.95	-0.71	6.954	-0.05
8	7.97	-0.38	7.970	0.00
9	8.91	-1.00	8.916	-0.07
10	10.04	0.40	10.053	-0.13
11	10.99	-0.09	11.019	-0.27
12	11.92	-0.67	11.905	0.13
13	12.95	-0.38	12.962	-0.09
14	14.03	0.21	14.038	-0.06
15	14.97	-0.20	15.004	-0.23
16	15.92	-0.50	15.940	-0.13
17	17.00	0.00	16.997	0.02
18	18.03	0.17	18.013	0.09

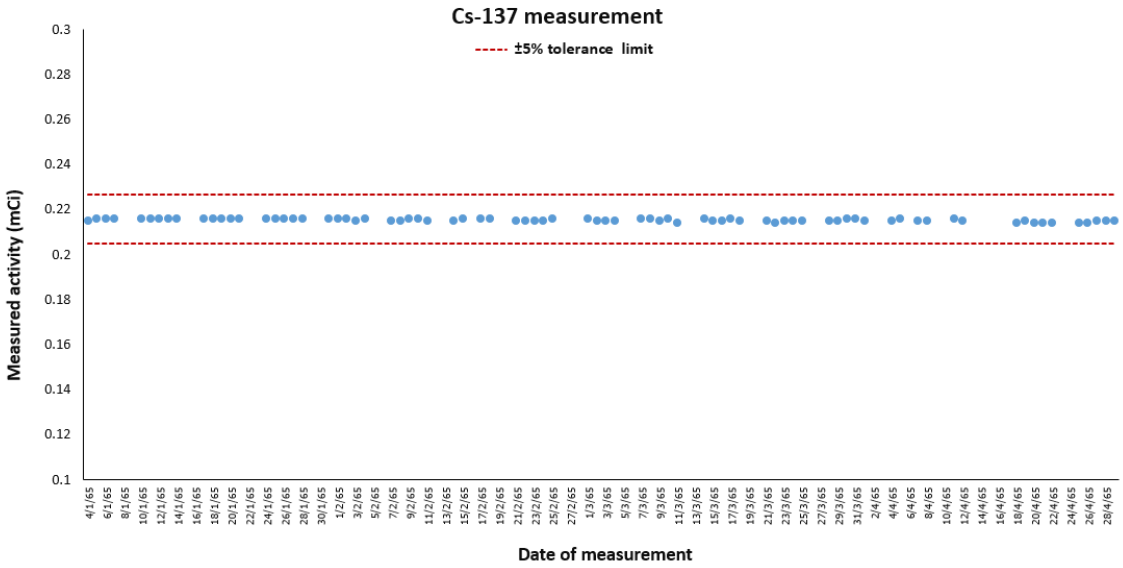

Figure 6. The daily measurement of the ^{137}Cs reference source was plotted against date and ±5% tolerance limit

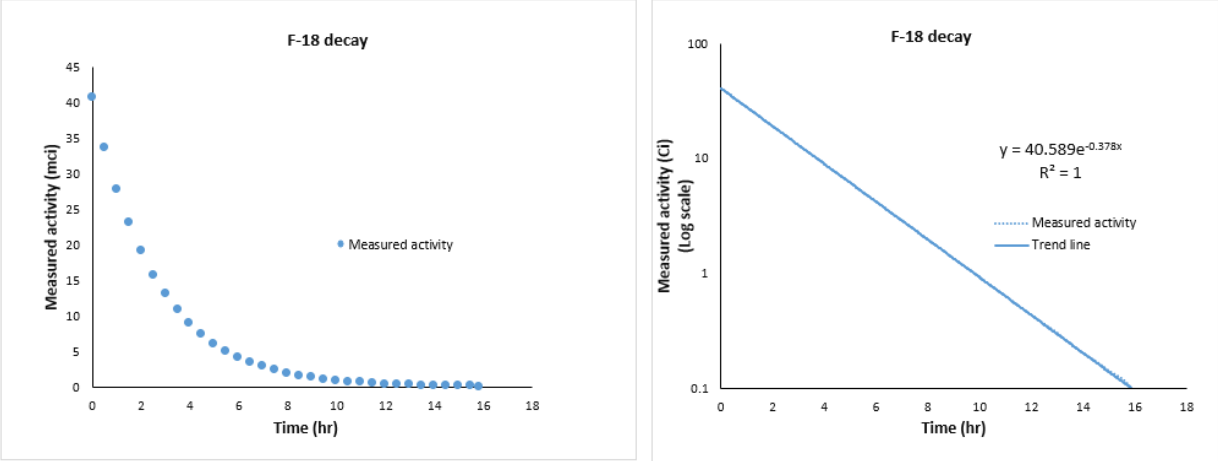

Figure 7 The relationship between measured activity against time. (Left) Linear graph plotted had an exponential decrease (Right) Semi-log graph plotted shown a straight line with good trend line fit.

Discussion

The quality controls of nuclear medicine instrument are extremely importance. This automated radiopharmaceutical administration had an integrated dose calibrator. Verification of this instrument was essential to ensure its function properly. In the same manner as the quality control of dose calibrator[6-7], we perform the precision test of the measurement by using ^{137}Cs as the reference source and obtained an average of 0.2145 mCi, with a standard deviation of 0.0005, as shown in table 1. The standard deviation was a summary measured of the differenced of each observation from the mean. This indicated that the values were closed to the mean. All measurements did not different from the mean greater than ±0.23%. The precision test was within acceptable limit of ±5%. The accuracy of ^{137}Cs measurement was calculated by comparing the mean measured value with the reference value (corrected for radioactive decay to the day of measurement). The accuracy test was 0.42%, this result was within acceptable limit of ±10%. Because ^{137}Cs had a long half-life of 30 years, daily measurements can be performed with a reasonable level of stability. The daily measurements activity of ^{137}Cs had been plotted on linear graph against date, as shown in figure 6. The reproducibility test was within the acceptable limit of ±5% of the actual value. The linearity response test was performed simultaneously with the regular linear test for the MedRad Intego, which is required quarterly. In addition, we used a close circuit camera to record the screen display of the MedRad Intego because it took a very long time for the activity to decay to 0.1 mCi, as shown in table 3. The measurements activity of ^{18}F-NaF were plotted against time on a linear graph and shown the exponential decrease. So, we transform to linear by plotted on a semi-log graph and fit this curve for trend line, as shown in figure 7. We obtained the equation from trend line as $y = 40.698e^{-0.379x}$ and the coefficient of determination (R^2) equal to 1, indicating a well regression line fit data. From trend line, determining the half-life of ^{18}F was 109.73 minutes, while the actual half-life of ^{18}F was 109.77 minutes. The difference between actual and determining half-life was 0.009%. The measured value differenced from expected value was an error of measurement. The percentage of error was high when activity of ^{18}F-NaF less than 0.43 mCi. The maximum error was 4.63% at activity of 0.12 mCi, as shown in figure 8. This automated radiopharmaceutical administration had the maximum injectable activity of 25 mCi and the minimum activity was 1 mCi. Therefore, the error from this measurement was not in the range of use. The manufacturer[8] did not recommend performing a geometry test because it had passed the IEC61145 (International Electrotechnical Commission) standard and the purpose of this integrated dose calibrator was

used for a single isotope: ^{18}F (e.g. ^{18}F –FDG, ^{18}F-NaF, etc.). The position of this isotope in the dose calibrator was fixed based on the design of MedRad Intego SAS (Source Administration Set).

The activity prescribed and the activity obtained by MedRad Intego had a maximum different of -2%, whereas the manufacturer's acceptance limit was ±10%. The comparison of activity obtained from MedRad Intego and measured by CRC-55tR dose calibrator (with decay correction) in the range from 1 to 18 mCi, as shown in Table 3, the maximum difference between MedRad Intego and CRC-55tR was –1.13%. In accordance with the guideline of the European Association of Nuclear Medicine (EANM), a net FDG activity can be administered by automated system within ±3%[9]. The relationship between the obtained activity and activity measured by CRC-55tR dose calibrator, as shown in Figure 9, was a straight-line with the equation y = 0.9991x + 0.0223, R^2 = 1. The result of a statistical hypothesis test using pair t test, the p-value was 0.046 at a confidence level of 99%. This indicated that the activity dispensed by MedRad Intego and measured by CRC-55tR dose calibrator was no statistically significant (p>0.01). Due to the high cost of ^{18}F–FDG, we are unable to perform testing up to a maximum activity of 25 mCi. ^{18}F-FDG dose injection is typically given at 0.11 mCi/kg according to the patient's body weight. Considering that the dose to be injected is 18 mCi, the patient's weight must be 164 kg. This situation has a very low chance to be occurred at the KCMH.

Conclusions

The integrated dose calibrator of this automated radiopharmaceutical administration was passed the quality control for precision, accuracy, reproducibility and linearity test. It confirmed that the integrated dose calibrator was well performed in measuring radioactivity of ^{18}F radiopharmaceutical. The desired activity was automatically prepared from the multi dose vial and injected into the patient. The activity obtained from this automated radiopharmaceutical administration was no statistically significant difference (p>0.01) from dose calibrator used for PET scans. This study was made confident and reliable in the used of automated radiopharmaceutical administration. It reduced the manual handling of ^{18}F-FDG. So, the radiation exposure to both nuclear medicine technologists and nurses who perform the injection of this radiopharmaceutical had been reduced. However, this automated administration was limit applicable to ^{18}F only.

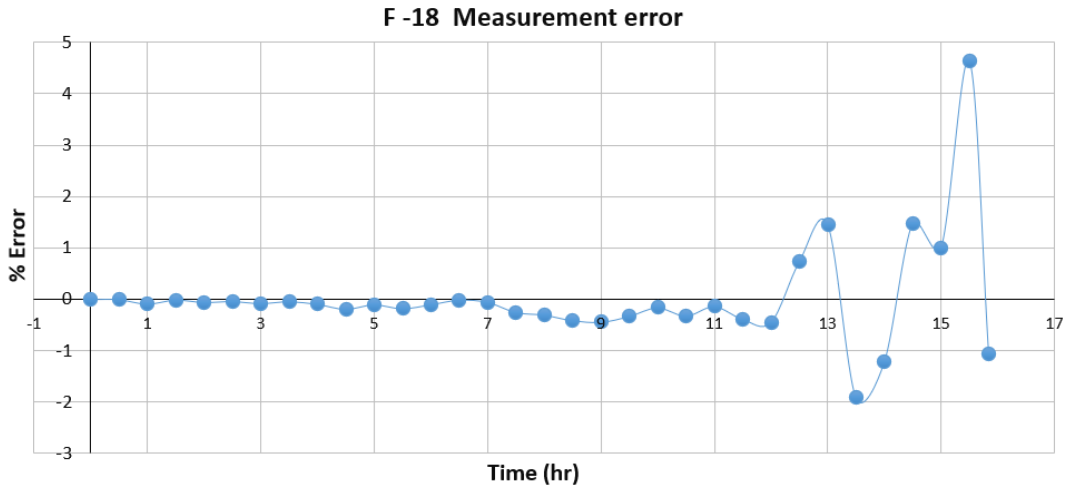

Figure 8 The percentage error between measured activity and expected activity against time.

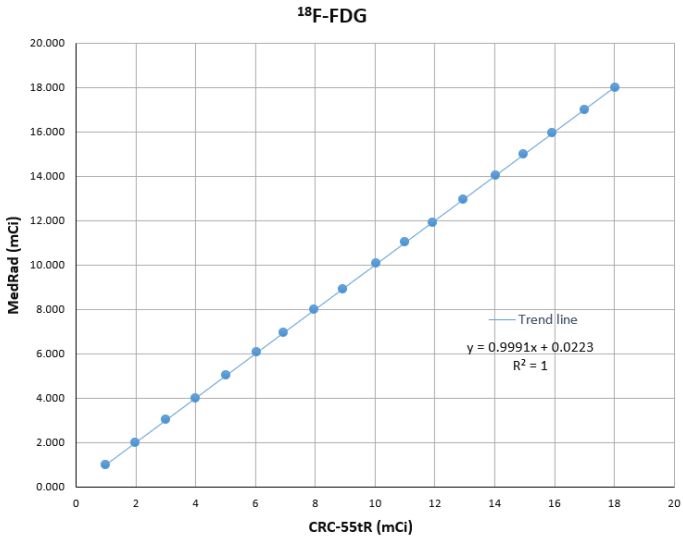

Figure 9 The relationship between the activity obtained from MedRad Intego and this activity was measured by CRC-55tR dose calibrator (with decay correction).

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