CLEANROOM PERFORMANCE TESTING IN HOSPITAL'S VASCULAR INTERVENTIONAL RADIOLOGY LABORATORY

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Abstract - A Vascular Interventional Radiology (VIR) laboratory is a hospital facility that requires cleanroom standards to reduce infection risks. In the VIR laboratory, laparoscopic surgery, known as minimally invasive surgery, is performed with the use of video imaging. This article describes a standard practice of conducting field measurements in an ISO Class 8 VIR laboratory. The measurements were carried out at rest conditions as described in ISO 14644-1 standard. The lab was equipped with High-Efficiency Particulate Air (HEPA) filters, and a vertically downward unidirectional flow system. A TSI 9310-02 airborne particle counter was used to measure three different particle sizes, namely, PM 0.5, PM 1.0 and PM 5.0. Meanwhile, an Alnor EBT 731 manometer was utilised to measure the average airflow velocity and pressure differential. On average, the recorded values of PM 0.5, PM 1.0 and PM 5.0 concentrations are 923351 particles/m3, 56963 particles/m3, and 551 particles/m3, respectively. While, the average measured values of supply air velocity, pressure differential, air temperature and relative humidity are 0.43 m/s, +0.79 Pa, 20.5ºC, and 63.3% respectively. This study shows that all the measured parameters are within the threshold values prescribed in the ISO Class 8 standard.

Keywords – clean room, field measurement, ISO class 8, vascular interventional radiology

I. INTRODUCTION

A Vascular Interventional Radiology (VIR) laboratory is a healthcare facility used for performing surgery and treatment, with the aid of image guidance. It serves as an essential treatment for acute vascular and solid organ injury patients [1]. The VIR treatment had a history of more than two centuries and was first performed in Germany for urethral orifice treatment. The VIR facility, however, was officially made available starting from the year 1947. Nowadays, this technique has become a rapidly expanding field in the healthcare discipline [2]. The advantages of VIR surgery compared to the conventional surgery are smaller incision size, minor injury to body tissues and muscles, minor post-operative scars and shorter healing time [3]. Moreover, complicated treatments, such as arterial occlusive, traumatic, and aneurysmal lesions are difficult to accomplish through conventional surgical techniques, however, via the VIR method, it becomes trouble-free [4]. According to Marin et al. [4], the success rate of the above procedures is significant, that is to say, above than 90%. Morris [1], Marin et al. [4], and Liu et al. [5], reported that the VIR techniques such as endovascular stent grafting have successfully treated direct vascular injuries. The VIR laboratory is usually equipped with an operating table, monitors, operating instrument trays, and an advanced medical imaging camera [3]. Other equipment such as an insufflation unit, uterine manipulators, atraumatic graspers, and a suction irrigation machine might also be available in the lab. Usually, the types of equipment depend on the treatment that is carried out.Most procedures performed in the VIR laboratory are Percutaneous Transhepatic Cholangiogram (PTC), Trans-Arterial Chemoembolization (TACE), Transjugular Intrahepatic Portosystemic Shunting (TIPS), and Radiologically Inserted Gastronomy (RIG) [6]. Recently, Halpenny et al. [6] reported that patients who undergo PTC procedures possess a high rate of infection (i.e., as high as 40 %); whereas, the infection rate for RIG schemes were reported to be as high as 30 % [7]. In 2015, Sutcliffe et al. [7] stated that the number of VIR surgeries was rapidly increasing each year. The increment justifies the need and the importance of reducing infection rates. Precautionary measures such as sterilisation techniques and a clean environment are essential for preventing and controlling the risk of infection [8]. Therefore, the ISO Class 7 cleanroom standard should be implemented in the VIR laboratory [9] to assure a clean environment, thus could reduce the concentration level of Particulate Matters (PMs) below the recommended threshold, which in turn improves the infection rates. As the effects of PMs amount on the bacteria counts and the infection rates are significant [10]. Recently, Romano et al. [11] claimed that PM 0.5 to PM 10 have a substantial influence on bacteria counts; Chow and Wang [12] reported that bacteria counts and the level of PM 5 to PM 10 are significantly related, and they show a positive correlation. Measurement procedures for quantifying PM 0.5, PM 1, and PM 5 are described in ISO Class 7 and 8 standards.The aim of this study is to demonstrate the actual process of quantifying cleanroom parameters in a VIR laboratory as described in ISO Class 8. This paper presents results of measured cleanroom parameters in the VIR laboratory of a private hospital located in Selangor, Malaysia. The cleanroom parameters compromised of

particle concentration level, supply air velocity, pressure differential, temperature, and relative humidity.

II. METHODOLOGY/ MODEL DESCRIPTION

In the present study, the measurement of cleanroom parameters was carried out in a VIR laboratory of a private hospital located in Selangor, Malaysia in June 2015. The measurement procedures complied with ISO14644-1 [13], IEST-RP-CC006.2 [14], and NEBB Procedural Standards for Certified Testing of Cleanroom [15]. Throughout the test, the conditions of the lab were set at rest and steady state. All the measuring instruments were well-calibrated to produce reliable data.

A. Description of the VIR Laboratory

The selected laboratory is classified as an ISO Class 8 cleanroom and is used for conducting laparoscopic surgery. The size of the lab is about 7.9 m (L) × 5.2 m (W) × 3.0 m (H), and the volume is 250 m3. Four supply air diffusers are mounted on the lab's ceiling. Each of them is equipped with a High-Efficiency Particulate Air (HEPA) filter which capable of producing unidirectional-downward air flow into the room. The HEPA filters capable of trapping 99.97% of particles with a diameter size of 0.3 and above [16-19].

Table 1 shows the type of equipment commonly available in the lab.

Equipment	Quantity	Dimension
LCD monitor	6	0.46 m (W) × 0.30 m (L) × 0.15 m (T)
Instrument tray	2	0.45 m (W) × 0.6 m (L) × 1.0 m (H)
Operating table	1	0.6 m (W) × 1.9 m (L) × 0.8 m (H)
Exhaust grilles	4	0.22 m (W) × 0.46 m (H)
Supply air diffuser	4	1.2 m (W) × 0.6 m (L)

W represents width, H represents height, D represents diameter, T represents thickness, and L represents length

Table 1: Description of the equipment in the lab

The detailed layout of the VIR laboratory and the arrangement of the equipment is shown in Figure 1.

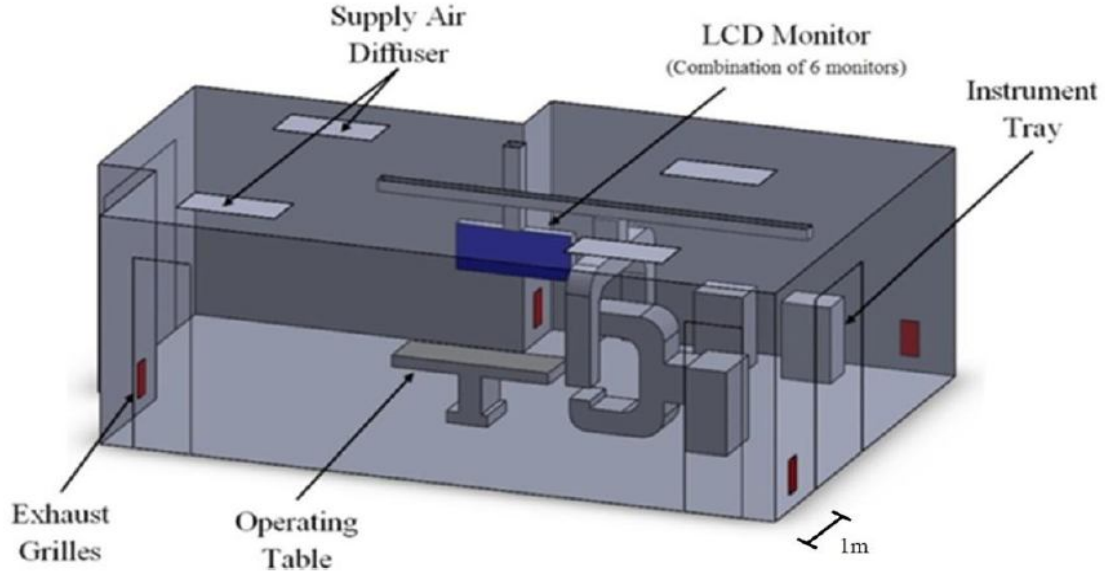


Figure 1: 3-Dimensional model of the VIR laboratory

B. Measurements of PM 0.5, PM 1.0, and PM 5.0

A TSI 9310-02 airborne particle counter was used to quantify the particulate matter of types PM 0.5, PM 1.0 and PM 5.0. The instrument has an accuracy of +/- 5 %, with a flow rate of 28.3 L/min. The counting efficiencies for respective PM are 50 %, 50 %, and 100 %. The measurement was performed at the height of 1.1 m above floor level because the airborne particulate matters are usually attracted to the open incision approximately at this height [17]. The PM count measurement was acquired in the sampling grids. The size of each grid was determined based on the IEST standard as shown in Equation (1), that is 30 m2 [20].

$$N = \sqrt{A} \quad (1)$$

where N is the minimum number of sampling locations, and A is the area of the cleanroom in a square metre. Figure 2 shows the plan view of the entire grids, where, nine sections of measuring points have been ascertained.

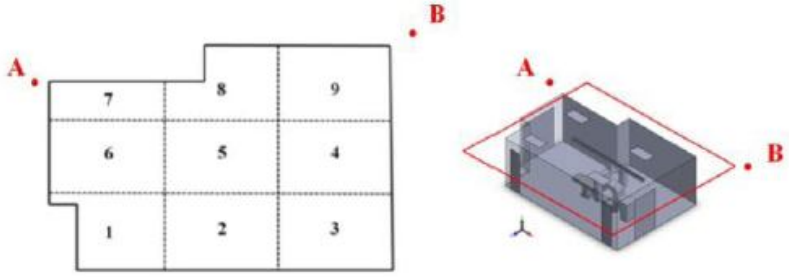


Figure 2: Plan view of sampling grids

C. Measurements of Supply Air Velocity and Pressure Differential

An Alnor EBT 731 manometer was used to the measure supply air velocity and pressure differential. The measurement procedures followed the ISO 14644-1 recommendation. The device accuracy for measuring the air velocity and pressure differential is +/-3 % and +/-2 %, respectively. A balancing airflow test was conducted before the actual measurement was made. Throughout the measuring process, all doors and openings remained closed, and a 10-second interval was set for each sampling. The velocity measurement was done twice at each sampling point. Figure 3 shows the locations of the air velocity and pressure differential measurements.

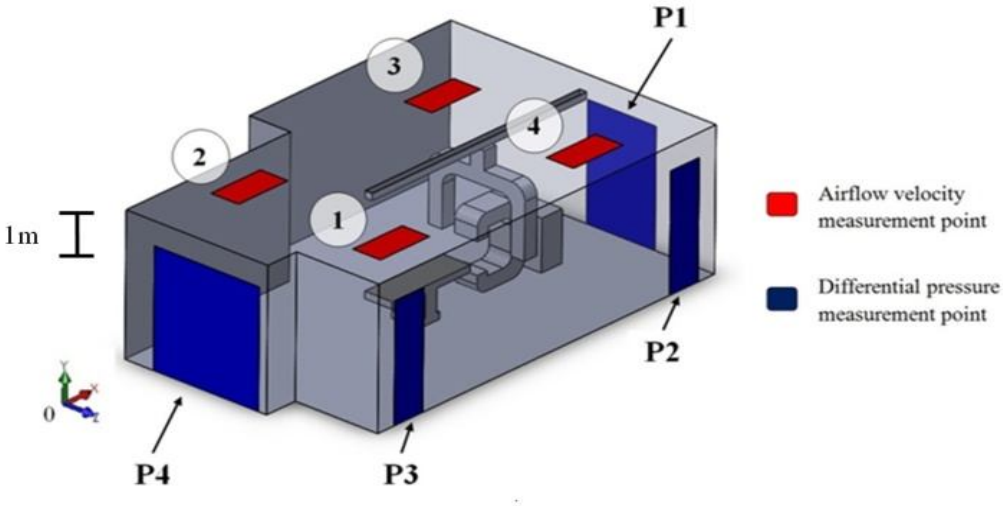


Figure 3: Sampling points for measuring supply airvelocity and pressure difference of VIR lab

D. Measurements of Air Temperature and Relative Humidity

A Testo 625 thermo-hygrometer was used to measure the air temperature and relative humidity (RH). The accuracy of temperature and RH readings is +/- 0.5 ºC and +/- 2.5 %, respectively. One day before the measurement was performed, the air-conditioning unit in the VIR lab has remained functional. During the measurements, all doors and openings were kept closed. The air temperature and RH measurements were done simultaneously in each sampling grid. Figure 2 shows the locations of the measurement.

E. Standard Deviation and Standard Error Calculations

Standard deviation is a measure of dispersion of measured data, whereas the standard error estimates the sampling fluctuation statistically. Both are formulated by Equations (2) and (3), respectively [21].

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n}} \qquad (2)$$

whereσ is the standard deviation, n is the numbers of measured data, $\bar{x}$ is the sample mean, and x_i is the measured value.

$$SE = \frac{\sigma}{\sqrt{n}} \qquad (3)$$

where SE denotes standard error, σ signifies standard deviation, and n indicates the number of the measured data.

E. 95 % Upper Confidence LimitCalculation

In an ISO cleanroom, the particle concentrations are measured in the sampling grids as described in the previous section and illustrated in Figure 2. The particle levels in each sampling grid should fall at or below the threshold limit as prescribed by the ISO classification. The average particle level for all the grids must remain at or below the threshold with a 95 % Upper Confidence Limit (UCL) if the total number of sampling grids are below nine. However, the 95 % UCL is not applicable to more than nine number of grids. Equation (4) estimates the confidence level of the measured particles concentration [13, 17].

$$95\,\%\ UCL = \bar{C} + F_{UCL} \times \frac{\sigma_c}{\sqrt{n}} \quad (4)$$

where UCL is the upper confidence limit, $\bar{C}$ is the mean value of particle concentration in particles/m3, FUCL is the factor of UCL, n is the number of samples, and σc is the standard deviation of the particle concentration in particles/m^3.

III. RESULTS AND DISCUSSION

Table 2 summarized the average values of measured particle concentrations and the standard deviation, standard error, UCL factor and 95 % UCL. On average, the recorded levels of PM 0.5, PM 1.0, and PM 5.0 are 923351 particles/m3, 56963 particles/m3 and 1184 particles/m3, respectively, where all the values are below the threshold prescribed in the ISO Class 8 standard. The average concentrations of PM 1.0 and PM 5.0 have also attained below the outset values specified in the ISO Class 7. According to studies done by several researchers, PMs are usually originated from personnel, patient and some equipment that contains gaseous [3, 22]. The UCL factors for all PMs are estimated as 1.9 as defined in Equation 4. A small value of standard deviation indicates that the variance between the individual data and the sample mean is irrelevant; whereas a low value of standard error shows that the sample mean is prone to the population mean

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	Measured concentration, particles/m^3			ISO Class 8 allowable concentration, particles/m^3		
	PM 0.5	PM 1.0	PM 5.0	PM 0.5	PM 1.0	PM 5.0
Average	923351	56963	1184	3520000	832000	29300
Standard deviation	97464	37065	551	-	-	-
Standard error	48732	18462	276	-	-	-
UCL factor	1.90	1.90	1.90	-	-	-
95 % upper confidence limit	985078	80437	1532	-	-	-

Table 2: Standard deviation, standard error, UCL factor and 95 % UCL for average values of measured particle concentration

Table 3 shows the measured supply air velocity inside the VIR, the average values, standard deviation and relative standard deviation. On average, the measured supply air velocity at the diffusers is around 0.43 m/s +/- 7.31 %.The air velocity values at all diffusers are within the recommended limits prescribed in the ISO standard that are between 0.36 m/s and 0.54 m/s. According to McNeill et al. [23] the average air velocity of the diffusers should not pass above the maximum and drop below the minimum limits as these conditions could induce turbulent airflow that can cause an increase of airborne particle inside a cleanroom space.

Diffusers No.	Velocity (m/s)		
	1st attempt	2nd attempt	Average
1	0.47	0.46	0.47
2	0.43	0.44	0.44
3	0.38	0.40	0.39
4	0.43	0.46	0.45
		Average (m/s)	0.43
		Standard Deviation	0.03
		Relative Standard Deviation	7.31 %

Table 3: Supply air velocity data inside the VIR

Table 4 summarised the measured differential pressure at four different locations. The recorded data shows that all the measuring locations registered a positive pressure difference between the lab and the adjacent zones, with the lowest and highest values of +0.79 Pa and +1.47 Pa, respectively. A positive pressure difference of at slightest 15 Pa is capable of guarding the airborne particles for penetrating into the

lab [9]. A negative pressure difference could be developed when the lab's doors are frequently opened and closed. As reported by Pankhurst et al. [10], they have carried out a test to determine the number of door opening events for a VIR lab. They found out that about 93 times occasions were recorded per surgical procedure. The correlation between differential pressure values and airborne particle levels inside a controlled environment such as VIR lab has an opposite effect. If the lab endured a negative pressure difference, the adjacent particles would quickly penetrate into the lab and finally could induce infection rates to the patients.

Location	Sampling Point	Differential Pressure (Pa)
Lab with respect to corridor	P1	+ 1.03
Lab with respect to corridor	P2	+ 0.79
Lab with respect to corridor	P3	+ 1.22
Lab with respect to technical room	P4	+ 1.47

Table 4: Lab Differential Pressure

The measurements of air temperature and RH were carried out in a duration of 1.5 hours at rest condition. On average, the recorded air temperature is about 20.5 ºC, with a deviation of 0.2 ºC. While the mean value of the air relative humidity is around 63.3 %, with a fluctuation of 0.2 %. Both values are within the safety limits prescribed in the ISO Class 8 cleanroom, that are, between 18 ºC to 22 ºC and 45 % to 65 %, respectively.

CONCLUSION

A Vascular Interventional Radiology (VIR) laboratory is a hospital facility that requires cleanroom standards to reduce infection risks. A field measurement was carried out to demonstrate the actual process of quantifying cleanroom parameters in a VIR laboratory as described in ISO Class 8. On average, the recorded levels of PM 0.5, PM 1.0, and PM 5.0 are 923351 particles/m3, 56963 particles/m3 and 1184 particles/m3, respectively. The mean value of the measured supply air velocity at the diffusers is around 0.43 m/s +/- 7.31 %. A positive pressure difference between the lab and the adjacent zones has been recorded, with the lowest and highest values of +0.79 Pa and +1.47 Pa, respectively. On average, the recorded air temperature is about 20.5 ºC, with a deviation of 0.2 ºC. While the mean value of the air relative humidity is around 63.3 %, with a fluctuation of 0.2 %. All the measured values are within the safety limits prescribed in the ISO Class 8.

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