Performance test of technical cleanroom clothing systems

Francesco Romano¹,*; Bengt Ljungqvist²; Berit Reinmüller²; Jan Gustén²; Cesare M. Joppolo¹

¹ Politecnico di Milano, Dipartimento di Energia, via Lambruschini 4, 20156, Milan, Italy.
² Chalmers University of Technology, Building Services Engineering, SE-41296, Gothenburg, Sweden

*Corresponding author email: francesco.romano@polimi.it;

SUMMARY

The work presented in this paper deals with aseptic cleanroom clothing systems performance and gowning procedures. The study had the purpose of evaluating the inert and viable airborne particle concentration shed by personnel when gowning a complete cleanroom clothing system suitable for aseptic operations at different washing, drying, sterilization (WDS) cycles. The tests procedure consisted of a normal working activity carried out in a stainless steel body box test rig. Inert and viable airborne contamination has been monitored continuously and in parallel throughout all experimental tests following aseptic procedures during the sampling task. Results have shown how WDS cycles, clothing size and personnel activity may influence the particle content shed by personnel and therefore the air cleanliness of an environment. Personnel working in clean environments might be aware of the importance of gowning system clothing and their procedures as well as the importance of training in operational behaviors in aseptic environments.

PRACTICAL IMPLICATIONS

Cleanroom technical clothing system evaluation into a body box test chamber under aseptic condition.
Different physical activity level influence the particle release rate of personnel into a clean environment.
The ageing factor slightly influences the particle barrier performance of a cleanroom clothing system.

KEYWORDS

Indoor air monitoring, airborne contamination, cleanroom clothing system, cleanrooms
1 INTRODUCTION

Products quality and the work environments aspects, as human health, are becoming important factors in many industrial and civil settings. (Lee et al. 2004; Saldanha et al. 2008). Cleanrooms and controlled environments are places where inert and viable particle concentrations are strictly under control both for air and surfaces.

In many clean production environments such as pharma, food, beverage, hospitals and etc., the control of inert and viable contamination is crucial and strictly ruled by proper standards and guidelines (EU Committee, 2008; US FDA 2004; ISO, 1999). HEPA (High Efficiency Particle Air filter) filtered air is commonly utilized for keeping the air cleanliness under the prescribed level while surface contamination are controlled by utilizing proper non particle release materials and components within clean environment. Apart the contamination generated by a process itself, within clean environments the main source of contamination is due to human presence. A person releases about 10 million particles/day (between 0.5-5 μm) and the release rate is 10,000 particles/min for a normal walk with civil garments. In a cleanroom environment, microbiological contamination is almost exclusively derived by personnel (Whyte and Hejab, 2007). Appropriate technical clothing systems may reduce the micro-organism content released by personnel in clean environments as stated by Romano et al (2015).

The main purpose of cleanroom clothing is the product and environment protection from possible airborne contamination. Common technical clothings used in cleanrooms are made of synthetic fabrics with high barrier performance against particles released from human body, e.g. personnel. However, clothing must also protect personnel from process contamination. In aseptic process where strict contamination control is required, the gowning procedure consists of in wearing a complete set of coverall, hoods, long boots plus ancillary accessories such as hair net, mask, goggles, double pair of gloves, socks. Cleanroom clothing system for aseptic process becomes an important tool for maintaining the inert and viable contamination as low as possible. Therefore clothing systems, disposable or more often reusable, after their usage undergo to a periodically washing, drying, sterilization (WDS) cycles before next use. Standardized and well-accepted methodologies for testing and measuring the performance of cleanroom clothing systems’ fabric are present and well accepted (IEST, 2011) even though they use different airflow rates for testing separately inert and viable airborne particle release. Many works have been carried out studying the cleanroom clothing performance in different test conditions (Whyte and Hejab, 2007; Carsten, 2011, 2015; Ljungqvist and Reinmüller, 2004). However, data obtained by those studies are not comparable due to different locations of sampling points, procedures and test airflow rates. Kasina et al. (2016), Ljungqvist and Reinmüller (2015) among others have tested the performance of different operating room suits in real conditions. However, there is still the need for a more precise, well accepted methodology for testing the entire cleanroom gowning system when used by personnel during normal activity work in aseptic areas in function of WDS cycles. Those deficiencies increase the level of uncertainty in choosing proper gowning systems and the possibility of uncontrolled microbial burden in aseptic areas. The aim of this work was the implementation of a test procedure and a complete gowning system test suitable for aseptic area of Grade B according to the EU GMP (EU Committee, 2008) in function of different WDS cycles. Experimental tests have been carried out in a body box test chamber with sampling locations and instrumentation kept in aseptic conditions throughout all tests. Viable and inert particle concentration has been measured continuously and in parallel throughout all tests.
2 MATERIAL AND METHOD

Experimental tests have been carried out in special clean environment designed for testing particle release/shedding for cleanroom clothing system dressed by human. The test rig used is composed of a body box chamber and a changing room connected by an internal door. Body box chamber as well as the changing room have dimension equal to 1220-1220-2440 mm (W-L-H) and are provided with a unidirectional HEPA H14 ceiling filter for their entire sectional area. Test rig is composed of stainless steel and glass, it has been designed following the specifications suggested by the IEST-RP-CC003.4 (IEST, 2011). A brief description of the test rig is shown in Figure 1. The test rig facility is located at the Energy Department of Politecnico di Milano.

![Figure 1. Layout out and experimental test rig setting](image)

Non-viable airborne particle has been measured by an Optical Particle Counter (OPC) (Aerotrak 9310, TSI Inc.). The OPC counting efficiency was 50% for particle diameters of 0.3 μm and 100% for particle diameters greater than ≥0.45 mm, (ISO, 2007). The sampling flow rate of OPC was 28.3 l/min. Particle size dimension chosen for test are ≥0.5 and ≥5 μm. Aerobic microbiological airborne contamination has been measured by a slit-to-agar air sampler with a d50 of 2.2 μm (FH6, Marcus Klotz GmbH) at a sampling air flow rate of 100 l/min. The sterile Petri Dishes used for sampling were of 90 mm in diameter filled with TSA agar media. For each test 2 Petri dishes have been used with a total air volume sampled equal to 1 m³ per plate. All sampling plates were incubated for at least 2 days at 32°C, and then 2 days at room temperature. All results are given in terms of CFU/m³. Air flow rate of body box and changing rooms have been measured by calibrated orifices designed according to standard ISO 5167 part 2 (ISO, 2003). The nominal airflow rate in the body box was set equal.
to 0.23 m$^3$/h. Temperature and relative humidity have been measured by a T&RH transmitter (HMD60Y, Vaisala; accuracy of measurements ±0.2 °C for temperature and ±2%or relative humidity). Thermo-hygrometric conditions during experimental tests were kept equal to 20±2°C and 50±10%. Body box and changing room were respectively in class ISO 3 and ISO 4 in at rest condition. The two chambers have been maintained in overpressure conditions with respect to the ancillary environments.

A test person, woman in good health condition, 32 years old, 60 kg of weight and 170 cm height, has been instructed according to a specific test protocol. Test person had to replicate 3 different standard movements within body box chamber. Every 3 minutes test person must simulate arm moving, knee bends and walking activities with a pause between each movements of one minute for a total test duration of 25 minutes. The movements and their frequency have been chosen in order to represent as much as possible normal working activity in aseptic process.

The technical clothing system tested was comprehensive of inner garment and socks, coverall, long boots, hair net, mask, textile hood, double pair of gloves and goggles. Except the polyester socks and the inner cotton garments, all materials used for each tests were beta ray sterilized. Coverall and long boots are made of Wind15 fabric (99% polyester and 1% antistatic with 5 mm conductive carbon stripes and area mass 102 ± 5% g/m²) by Alsco Italia srl. Inner garments, coveralls and boots are reusable while the remaining material was disposable. Three WDS level chosen for tests were 1, 30, 60 which represent respectively the new, half-life and end-of-life time of the gowning system. Related to boots, the maximum allowed WDS cycles was set to 20 due to the plastic part of them, which is more sensitive to the beta-ray sterilization. Five experimental tests for each WDS cycle have been carried out by the same person. Gowning system size tested were M and L. Experimental test rig and instrument were properly cleaned and sanitized by means of hydrogen peroxide vapor before each test while for test person and material sanitization was used a sterile solution of water purified and isopropyl alcohol at 70%. Viable and inert particle concentration has been measured continuously and in parallel throughout all tests.

Results have been expressed in terms of particle concentration (pp/m$^3$) and colony forming unit (CFU/m$^3$) per cubic meter of sampled air, respectively for inert and viable contamination. The impact of a human being on clean environment contamination has been evaluated through the source strength (SS) concept. The source strength is a valuable tool in describing the protection efficiency of clothing systems against particle shedding by a certain number of people $N$ gowned. SS is obtained, in this case, by multiplying the max concentration obtained $C$ (in pp/m$^3$ or CFU/m$^3$) times the airflow rate of the body box $Q$ (m$^3$/s). With the assumption of no air leakage into the body box and the HEPA filters having particle and microorganism retention efficiency close to 100%, and verified a zero contamination within the body box, the simplest possible expression, which applies the dilution principle, can describe the source strength as:

$$SS = \frac{C \times Q}{N}$$  \hspace{1cm} (1)

Depending on the concentration measured $SS$ can be expressed either in terms of particles released by a person in a second (pp/person/s) at fixed particle size dimension or colony forming unit per person in a second (CFU/person·s).
3 RESULTS

The average particle barrier performances of an aseptic cleanroom clothing systems tested are shown in Table 1 in terms of particle shedding and particle source strength (PSS) by a person at two different particle size dimensions (≥0.5 and ≥5 μm) in function of different WDS cycles.

Table 1. Average values of airborne particle shedding and particle source strength by a person gowning an aseptic cleanroom clothing system under different WDS (1, 30, 60) for particle size ≥0.5 and ≥5 μm. Min and max values presented within brackets.

<table>
<thead>
<tr>
<th>Particle Concentration [pp/m³ of air]</th>
<th>1 WDS</th>
<th>30 WDS</th>
<th>60 WDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>particle size ≥0.5μm</td>
<td>5912 (282-26431)</td>
<td>8578 (565-32932)</td>
<td>6770 (530-26572)</td>
</tr>
<tr>
<td>particle size ≥5μm</td>
<td>87 (0-671)</td>
<td>125 (0-530)</td>
<td>92 (0-636)</td>
</tr>
<tr>
<td>Particle Source Strength [pp/person·s]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>particle size ≥0.5μm</td>
<td>1360 (65-6079)</td>
<td>1973(130-7574)</td>
<td>1.557 (122-6112)</td>
</tr>
<tr>
<td>particle size ≥5μm</td>
<td>20 (0-154)</td>
<td>29 (0-122)</td>
<td>21 (0-146)</td>
</tr>
</tbody>
</table>

The working activities simulated during experimental tests carried out gave different particle source strengths for one person completely gowned in function of WDS cycles of the clothing systems tested as shown in Figure 2 and Figure 3.

Figure 2. Average particle source strength (particle size ≥0.5 μm) in function of working activities at different WDS cycles.
Comparative experimental tests have also been carried out in order to evaluate the increment of airborne particles released by a person when gowning a complete set of cleanroom clothing system of the same quality, but with one size larger than his normal size, i.e., L size vs M size, at different WDS cycles (60 and 30). Results of these tests are shown in Table 2, as percentage increment of particle content of a size L clothing system set compared with the same M size set.

Moreover, the value of the air microbiological contamination during all the experimental tests carried out, a different WDS cycles (1-30-60), was always equal to <1 CFU/m³. Therefore, it has been done the conservative assumptions that the viable source strength released by the test person within the body box was equal or less than 0,23 CFU/person and second.

### 4 DISCUSSION

Based on the results of experimental tests carried out the total airborne particle released (≥0,5 and ≥5 μm) by one test person dressed with a specific gowning systems and procedure during simulated working activities seems to be slightly affected by the WDS cycles number. More in detail, the clothing system with 1 and 60 WDS cycles obtained similar values of particle release while clothing systems at 30 WDS cycles had on average particle release values 35% higher than clothing at 1 and 60 WDS cycles. The different particle release of clothing systems at different WDS cycles may be caused by two main factors: the attrition of the
woven, which increases with the number of WSDs until a maximum peak around the half-life period which decreases the barrier effect, and the “cake effect” of the woven, which on the contrary increases with WSD. However, the aseptic gowning systems tested have produced source strengths contents, for all the WDS cycles tested and for both particle and aerobic microbiological, so that the threshold limit values of the classification grade B at ”operational occupational state” would be respected also with the presence of more than a person in cleanroom environments normally designed for such a grade. The knee bends movement has been the test activity with the high particle release, and therefore the highest particle source strength as shown in Figure 2 and 3. However in between of the two high frequency activities, knee bends and walking, the particle content released is still high and directly proportional to the preceding activity. The particle penetration performance of the gowning system tested have a similar trend for both particles size of $\geq 0.5$ and $\geq 5 \mu m$. Results in Table 2 show how a test person replicating the same working activities with the same cleanroom clothing system and gowning procedure but at different clothing size may have diverse impact in terms of particle contamination. Precisely, a test person who normally wear a size M gowning system, when tests are performed with a gowning system of size L, the contamination in the test environment is increased. This increment in particle contamination is even more accentuated if the comparison is done between contamination with L size vs the M size at 60 WDS cycles, where the average increment of particle release is 98 % higher than the concentration released by the same person with the size M. In this case, the clothing system with the higher number of WDS has also lower performance in comparison with the other WDS cycles. The microbiological contamination monitored during the tests has been almost constant and with low value so that the viable source strength has been assumed constant. The low value of the viable source strength may be ascribed to many factors such as the good quality of cleanroom clothing system and gowning system together with the repeatability of the microbiological air sampling task. Moreover, in these tests, all instrumentation as well sampling task and sanitization process were kept under a sterile cabinet which gave the possibility to avoid the risk of external and cross contamination for both air sampler and Petri dishes used.

5 CONCLUSIONS

The experimental tests carried out in the body box test chamber following a precise test procedure have shown the influence of WDS cycles and size of cleanroom clothing system on particle release by personnel. Moreover, results have shown that a person dressed with a good aseptic cleanroom clothing system may impact on the contamination of a clean environments depending on his working activity, the decontamination time elapsed by two activities. Therefore, in such environments is crucial that personnel be aware of the potential they in terms of particle contamination also when they are in still activity. The risk of particle contamination in aseptic cleanroom may be kept under acceptable limit value with appropriate cleanroom technical gowning system and procedures and even more by means of a well instructed personnel for aseptic cleanroom operations.
REFERENCES

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