The Impact of Cleanroom Behavior on Contamination Control

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Cleanrooms are used to prevent unwanted contamination of products. People are the major source of particles and a fraction of these particles carry micro-organisms. Cleanroom behavior consists of 2 aspects: First, the various procedures that are in place to minimize the impact of people and second, the correct behavior of personnel that are executing these procedures. Contamination control starts with a risk assessment followed by a design of the contamination control solutions. After the contamination control solutions are established the effectiveness of the contamination control solutions during operation should be demonstrated by a monitoring program. In this paper, both aspects of cleanroom behavior will be addressed.

Introduction

A cleanroom with a proper cleanroom installation reaches in the “at rest” occupancy state an airborne particle concentration that is determined by the design and construction of this installation. The particle deposition rate of macroparticles (> 5 μm) will be zero. As soon as people come into the cleanroom, the particle concentration in the air increases and deposition of particles will occur.

In a cleanroom, people are necessary in order to perform complicated operations that cannot be done by machines in an economical way. People can make decisions based on their observations and acquired measurement data and adapt their operations accordingly.

The impact of human contamination and contamination by human activities should be limited by developing and implementing proper operational procedures. In some cases, it is not possible to reach the required cleanliness level and then machines (robots) in separate cleanrooms or clean zones (mini environments) are used to execute the manufacturing process or an intermediate solution with separative devices – like glove boxes – is applied.

To control the impact of people, procedures for permission, gowning, entering, cleaning, working, transferring goods and leaving the cleanroom are set up. Personnel should be trained regularly and motivated to execute these procedures in a proper way. In this paper both aspects will be addressed.

Risk of Product Contamination

The first step of a risk assessment is to determine what could be harmful for a product (or patient) during the process steps that are required to reach the goal of the executed process steps. The way to perform this type of analysis is described in [1, 2]. The result will be a list of critical locations at which the contamination of particles of a specific nature and/or size should not be transferred onto a critical product surface. For each type of contamination and at each critical product surface, the severity should be determined. The contamination control solution should limit (control) the chance of the unwanted contamination to be transferred onto the critical product surface.

There are 2 contamination mechanisms: First, the transfer of particles from the air or the deposition of particles and second the transfer of particles by contact with an unclean surface or medium. Contact surfaces will be contaminated by both mechanisms. In the end, the particle deposition rate in the critical environment is the major factor that should be controlled.

Particle deposition is caused by particles in the air that cannot be removed by the ventilation system. These particles come into the air by the introduction of unclean air and by the transfer of particles from surfaces into the air. The transfer of particles from surfaces arises from unclean surfaces and from particle generating surfaces. Surfaces generate particle by wear, friction, shedding and aging.

In contamination control, the deposition rate of particles is considered. The result of particle deposition is sometimes called particle fall out. The relation between the particle deposition rate and the number \( N_{DC}\) of unwanted deposited critical particles \( \geq Dc \ μm \) onto a critical product surface \( Ac \) at a specific location is given by:

\[ N_{DC} = R_{DC} \cdot Ac \cdot T \]

where \( R_{DC} \) is the particle deposition rate of particles \( \geq Dc \ μm \) during exposure time \( T \). \( T \) is in fact the time during the "operational occupancy state" since there is no particle deposition of macroparticles in the "at rest" state.
Contamination by contact transfer will not be quantified here, but it should be clear that all potential contact surfaces like tools, product holders, benches, hand, packaging etc. will be contaminated by particle deposition after cleaning and/or unpacking.

Particle deposition rate R is expressed in the number of particles per area per time (number/m²/s), see also [3–5].

The particle deposition rate depends on the local air cleanliness (concentration C of particles per m³) and the particle deposition velocity u:

\[ R = C \cdot u \]

The particle deposition rate will cause a change of surface cleanliness by an increase of the concentration \( \Delta C \) of particles per m² during exposure:

\[ R = \Delta C \cdot T \]

The particle deposition rate is determined by the activity of people and the total number of macroparticles in a cleanroom. Particles > 20 μm can only be removed by cleaning. If there is no proper regular cleanroom cleaning, the total number of particles on surfaces will increase. Therefore, in combination with the activity by people, the particle deposition rate will increase.

**Contamination by Humans**

A person sheds almost one billion particles per day. This is not a continuous process but a collection of events depending on the activity of a person. Most of these particles will be kept inside the clothing. In a cleanroom, a person wears special cleanroom garments that act as a simple filter (sieve with variable holes). The transmission of particles through these garments depends on the occlusivity of these garments and the quality of the fabric.

The generation of particles by a person in a cleanroom depends on the efficiency of the barrier function, but also on the amount of particles carried on the outside of the garment. The number of particles on the outside depends on the changing frequency, changing procedure and cleanliness of the changing room[1].

The cleanliness of the changing room depends on the number of people with street clothes in the changing room and the cleaning program of the changing room. The logistics are also important. If a person takes the cleanroom garment off, many particles will be distributed into the air. If another person puts a clean garment on at the same time, many particles from the person leaving the cleanroom will come onto the person that is preparing to enter the cleanroom. Furthermore, the number of changing stages in the changing room will affect the amount of cross contamination. If people wear cleanroom garments first, the particle load of these garments is much lower. Additionally, the use of special changing gloves will reduce the particle impact. By the use of undergarments, the cross contamination and the transfer through the cleanroom garments will both be decreased.

A rough estimate of the impact by people dressed for a cleanroom can be made by using a simplified empirical relation made by the author:

\[ N_0 = N_1 / (P^D) \]

where \( N_0 \) is the emission of particles ≥ D μm by a person per second (D ≥ 1 μm). It is assumed that the particle emission of a walking person in street clothes is about 100,000 particles ≥ 1 μm per second. P is the garment performance factor of the garments used. P is about 4 for a cleanroom smock with head and shoe covers, 20 for a coverall and 100 for complete cleanroom garments including undergarments[2]. In case there is no protection \( P = 1/D \).

1) In some cleanrooms an air shower is used to reduce the number of particles on the outside of the garments. The effectiveness is determined by the design of the air flow, the initial contamination on the garments and the residency time of the person. There are no data available of the impact of air showers on the particle deposition rate.

2) As an example, this relation leads to the emission of 200 particles ≥ 5 μm per second when wearing a coverall with \( P = 20 \) and an emission of 8 particles ≥ 25 μm per second.

It should be clear that the impact of personnel can be decreased by selecting the entering procedure, the garment performance factor and the layout of the changing room. The result is strongly influenced by the number of people since the shedding and cross contamination is proportional to the number of people. The better result will be more expensive. Therefore, a compromise is made in practice. This compromise depends on the accepted particle deposition rate and airborne concentration of particles. In micro-biological applications with strict environmental requirements, often the better entrance procedures are applied. In technical applications, procedures are balanced with the number of accepted rejects. However, the knowledge to understand the relation between contamination control solutions and performances is not always available or present [6, 7].

**Contamination by Human Activities**

Human activities in a cleanroom cause contamination in many ways. The particle generation has been described above. The disturbance of air flows by people will cause the local re-entering of particles from unclean surfaces. Particles are transferred from and to surfaces when contact is made by touching these surfaces. Movements of people will cause the re-entering of particles from their own garments and body surfaces.

When the air supply in a small cleanroom of 80 m² with one person is 480 m³/hr (6 air changes per hour), the airborne concentration \( N_0 \) will be 3,600*200/480 = 1,500 particles ± 5 μm per m³, which is within an air cleanliness level of ISO 7 in operation. If the supply air is increased to 3,600 m³/hr, \( N_0 \) will become 300/m³ which is within ISO 6 (ISO 14644-1). Most particles ≥ 25 μm will be deposited on surrounding surfaces. Say the surrounding surface area is 36 m² then the particle deposition rate \( R_{dp} \) for particles ≥ 25 μm will be \( 8*3,600/36 = 1,000 \) particles ≥ 25 μm per m² per hour. During 6 h of operation the average surface cleanliness will change from SCP 4 (after cleaning) to \( \log_{10}(10,000 + 6*1,000*25) = \) SCP 5.2 (ISO 14644-9).
Furthermore, people transport particles throughout the cleanroom by moving around and by ejecting particles by footsteps. When moving slowly, this impact will be lower.

People must be aware of the critical locations and moments in the manufacturing processes and their own impact on contamination. This awareness should help to avoid wrong behavior in the neighborhood of the critical product and tool surfaces.

**Contamination Control Solutions**

The basics of the contamination control solutions are the control of the introduction of particles into the critical zone, the removal of airborne particles with a cleanroom installation and the removal of the deposited macroparticles from all surfaces by frequent cleaning.

The cleanroom installation is designed in such a way that the concentration of particles up to 5 μm remains within the cleanroom class limits for 95% of the time at all locations during operation. Since people are the main source of airborne particles, the number of people and the selected garment type etc. should be known in order to make a dedicated design. For the classification of air cleanliness levels, ISO 14644-1:2015 [8] can be used.

The cleaning program should be designed in such a way that the concentration of particles on all surfaces should stay within a specified surface cleanliness limit. The surface cleanliness levels are described in ISO 14644-9:2012 [9]. The surface cleanliness specification for critical surfaces like those of tools could be stricter than that for floors.

The particle deposition rate is influenced by the way the cleanroom is used. It can be controlled by describing various operational procedures. A high particle deposition rate leads to a higher concentration of particles on surfaces. Unclean surfaces in combination with human activity lead to higher particle deposition rates. In order to control the particle deposition rate, the introduction of macroparticles should be limited and the cleaning program should be keeping the surface cleanliness within proper limits. The VCCN Guideline 9:2013 could be used to express levels of the particle deposition rate [10–12].

In a given cleanroom the operational procedures will determine the particle deposition rate level and therefore influence the risk of unwanted product contamination. The particle deposition rate can be controlled by designing procedures that limit the introduction of particles and the total surface cleanliness by cleaning. Various procedures could be optimized by establishing the relation with the particle deposition rate. This will require more research. Cleanroom procedures should be made for:

- The entry into the cleanroom
- The use of garment and the changing of garments
- Bringing of goods into the cleanroom
- Cleaning procedures
- Cleanroom behavior
- Working procedures
- The exiting of the cleanroom

When these procedures are made during the design phase, the layout of the clean facility can be optimized for the execution of the procedures.

**Demonstrating Control**

When the cleanroom installation and the operational procedures are established it is important to monitor the relevant cleanliness attributes to demonstrate control. The air cleanliness can be monitored with particle counters. They give information on the cleanroom installation and the emission of particles up to 5 μm.

The surface cleanliness could also be measured at critical locations. As-
Summing the cleaning procedures are sufficiently effective, it is sensible to measure this just before cleaning. This will show whether the cleaning frequency is too high or too low.

To demonstrate the execution of the operational procedures, the particle deposition rate should be monitored at critical locations. This can be done with witness plates with known surface cleanliness and measured surface cleanliness after sufficient exposure. In situ (and real time) particle deposition monitors could be used as an alternative [12–14].

In case the monitored particle deposition rate level is too high, either the execution of the operational procedures or the procedures themselves should be improved. To determine which operational aspects should be improved, further analysis of particle deposition rate data should be executed. The most important information is given by the moments of particle deposition and the size distribution of the deposited particles. This distribution can be compared with the theoretical particle size distribution that belongs to the required particle deposition rate level. For example, the particles ≥ 100 μm are relatively high when compared to this distribution. Then the cleaning of cleanroom and equipment surfaces should be improved. If the number of particles between 30 and 100 μm are relatively high, the impact of people should be reduced by improving the entrance and associated procedures.

Monitoring data will demonstrate the need for improvement of the execution of operational procedures or the improvement of the operational procedures.

**Achieving Required Human Behavior**

Adequate operational procedures should be in place in order to control the impact of cleanroom behavior of people on contamination control. These procedures should be such that when everybody applies them in the right manner the air cleanliness and particle deposition rate levels stay within the set limits.

To achieve the right execution of these procedures, regular training of anybody who enters the cleanroom is required. Furthermore, people should be motivated to follow these procedures. Motivation is part of a company’s culture and should receive continuous attention. When procedures differ a lot from the natural behavior of people, the quality of the execution will slip. Therefore, good execution should be rewarded and wrong execution should be corrected. The regular refreshing of the execution instructions should prevent slipping. Especially anybody in a managerial position should be aware of giving the right example. Therefore management, that occasionally will enter the cleanroom, should also be trained regularly. Display of real-time particle deposition will create awareness.

**Conclusion**

When writing this article, the author realized he was describing the ideal situation. In practice, improvisation and common sense are required to achieve proper results. The world of contamination control needs much more related data to be able to design and realize proper dedicated solution.

Many cleanrooms are overdesigned and too much air is circulating throughout the cleanroom, whereas the operations could be much more effective. This will cost a lot of energy. The impact of the operations is only partially visible when monitoring with particle counters only. A particle deposition monitoring system will help to collect data that can be used in risk evaluation. Moreover, the system can also show the impact of changes in the operational procedures. In cleanroom for micro-biological purposes, particle deposition rates will be proportional to settle plate data and will therefore also be useful to monitor the operational quality.

**LITERATURE**


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