The world of ISO 14644-5 operations

By Philip van Beek – Contamination Q & A

Introduction

In the world of cleanroom technology, the standard ISO 14644 is an important part of the daily work with clean rooms. The standard ISO 14644 has several extensions, namely extension 1 to 16. With each extension a specific part is developed as a specialty. Anyone who is in the field of clean room technology is aware of these standards. The standard ISO 14644-5 Operations is specifically concerned with how one should deal with the cleanroom operations.

Points of attention

When designing a cleanroom for a production facility if that now being pharmaceutical, micro-electronics, food or an operating theatre, the main argument which must be taken into account is to prevent product contamination. We are talking about product contamination and cross-contamination between different products. Specifically when the product is exposed to the ambient air deserves special attention and should be kept clean. The attention is in the early stages and is mainly on the design of the air treatment installation and the filtration of the supply air to the cleanroom. The factors which in addition to the control of air classification are important after the cleanroom is realized, are the clothing discipline and discipline of the people who work in the clean room. Finally, the cleaning and maintenance are important components of the success of the clean room in preventing product contamination. In most cases this even has the most influence on the correct working of the cleanroom.

Clothing discipline

Cleanroom clothing has various functions, first and foremost, the most important is protection of the product. The first choice that must be made is which cleanroom garments will be used. What clothing material are we going to use as a barrier? Which features should the material to be used have? Another important part which is often forgotten is how much we're going to be covering of
the particle generating body. Will we choose only for a haircover with overcoat or for a complete overall? The human body generates continuous particles by hair loss, scattering dead skin particles, exhaled air and saliva. The human is the biggest polluter in the clean room and an acceleration of the activities gives an increase in the issuance of particles by human. Clothing ensures that the product is protected against this pollution. Except that the clothing serves as a filter for the pollution of the human to the cleanroom, there should be great attention for the outside of clothing. This should also be kept clean. There may be residue of the pollution on the outside of the clothes be left and then cause cross-contamination. In addition to put on the clothing there should be attention for the fact that when the clothing is eventually put on and one is in the clean room at work, that the clothing does not come against surfaces inside the cleanroom. At the time that the outside of the clothing comes in contact with a wall portion there will by contact transfer particles on the outside of the clothes and in this way can be transported to the product and then contaminate the product. Also the swap rate is a concern to prevent unwanted contamination. Washing the cleanroom garments after use should be done in therefore equipped laundries. The clothes will have to be checked at regular interval on the degree of contamination control characteristics.

Behaviour discipline

Operators should be instructed to enter the clean room and also in the everyday life they will comply with hygiene rules as soon as the operator with the right clothes enters the cleanroom, the discipline regarding the behavior in the clean room can be a possible contamination of the products in the cleanroom. The speed with which activities are carried out is an important aspect of the behavior. More movement gives a greater chance of spreading of particles and micro-organisms in the clean room. In addition to moving the focus should be to the specific rules in the cleanroom. Each application and each company has its own procedures, these procedures are specific to the application per cleanroom. It may even be the case that in a cleanroom complex there are different procedures per process which takes place in the various separate cleanrooms. If one has experience at a company working in the clean room then one must still be trained.
In addition to the operators you need great attention to other visitors of your clean room environments, this can be a great source of contamination. Think first to the external cleaning company, are they properly trained in the behavior which is desired in the clean room? We talk about this group of people who still belong to a manageable aspect of the people who are in your cleanroom. A much trickier aspect are the people who enter with you occasionally, namely test staff, technical service, service mechanics, service engineers and suppliers. Are these people aware of the rules of conduct in your cleanroom for example in the area of smoking, eating, drinking and wearing jewelry. Do they know, for example, that everything needs to be cleaned before it can be introduced in the clean room? Everything must be focussed to prevent contamination in the clean room, high standard of awareness is important.

**Risk assessment**

The considerations about clothing discipline and behavior discipline are part of the quality risk management system. It should be ensured that there is a high level of assurance that potential risks are taken into account as efficiently as possible. The standard ISO 14644-5 has in Annex A attention to risk management. Here specifically the standard mentions about how to determine the contamination risks. As possibility for determining risks 14.644-5 the ISO calls the following methods:

- # Hazard Analysis Critical Control points (HACCP)
- # FMEA (Failure Mode Effects Analysis)
- # FTA (Fault Tree Analysis)

To prevent airborne particles in the clean room there should be a coherent process. Beside that the outside air needs to be cleaned, there are many other aspects that should be taken into account. This means that as end filters HEPA or ULPA filters should be applied there. In addition, it will be come essential to eliminate external sources of pollution of the surrounding areas to the cleanroom. In the space itself we need major attention to reducing contamination. The entire architectural construction should be designed for contamination conrol. The largest source of airborne particles in a cleanroom are the people. These generate both living and non-living particles. That the movement intensity contributes to the distribution of particles is obvious. These particles are skin particles, its particles, cosmetics-particles, clothing particles, perspiration and breathing particle emissions. A total of measures should ensure that the emission of particles is reduced and is as low as possible. This can be achieved by training. But also incidental visitors should be trained. Preferably training is done by an independent trainer. These elements should be taken in account at the making the risk assessment and can be checked with a clear list (1).
Conclusions

Preventing unwanted contamination is the main focus of attention when designing and working in cleanrooms. To protect efficiently in the different phases of production there are levels in purity. In addition to a correct design, the way of dressing and the behavior of the people in the clean room is essential for the cleanliness levels which have to be achieved. This means that there must be quality risk management. An important part of this is training of the people who work in the clean room and people who are there occasionally.

Literature:

1. Opzetten Normenkader – Contamination Q & A juli 2009
3. ISO 14.644-5 - operations
4. VCCN syllabus Cleanroom Gedrag Cursus
5. De wereld van compliance- Philip van Beek, VCCN magazine

TEKST ISO 14644-5

4.1.3 a system for training personnel in cleanroom procedures shall be instituted. A method for monitoring compliance to those training procedures shall be specified

4.1.4 a documentation system shall be maintained to provide evidence that all personnel have received suitable levels of training for their assignments

4.3.4 Cleanroom personnel shall be trained to conduct themselves in a manner that minimizes generation of contamination which can be transferred or deposited on or into the product.