Methods to keep a product clean

Koos Agricola

Abstract

Contamination control concerns methods to keep a product clean. For this reason the cleanliness of the surface of a product is expressed in terms of particles and also chemicals. Products can be contaminated by deposition or contact transfer. Deposition depends on the concentration of particles in the air and their deposition velocity. Large particles have a high deposition velocity and their concentration depends on the way the cleanroom is used. Smaller particles have a low deposition velocity and their concentration depends on the airflow. Another contamination mechanism is by contact with dirty surfaces, these having been previously contaminated by deposition. Chemical substances can condense or adsorb onto surfaces or they can be transferred by contact. Contamination control solutions include the provision of a controlled environment that is kept clean by flushing with filtered air and by regular cleaning of all surfaces. The most commonly used ventilation system is dilution with non-unidirectional airflow. Higher grade cleanrooms operate by displacement with unidirectional airflow. Classification of cleanrooms in accordance with ISO 14644-1:2015 is briefly described including the treatment of macroparticles with a threshold size between 5 µm and 20 µm. Surface contamination by particles that can be even larger is covered by ISO 14644-9:2012 and chemical contamination by ISO 14644-10:2013. A section on risk assessment with respect to particles introduces the concepts of particle deposition rate (PDR) and latitude. Latitude is the process window between the initial surface concentration and the final acceptable surface concentration. These concepts are illustrated by a worked example. PDR measurement methods are described, then how to establish control, how to treat process equipment and how to demonstrate control.

Introduction

Every year more new contamination sensitive products (sensors, actuators, displays, smart devices, medical devices and manufacturing tools etc.) are developed. The vulnerable surface area of many of these products is increasing. Therefore there is a growing need for clean manufacturing methods in the coming years. Next to new manufacturing methods more dedicated contamination control solutions are required to meet the future challenges.

Cleanroom technology and contamination control are applied to keep the surfaces of products sufficiently clean. To select proper methods to keep a product clean one needs to understand the functional requirements of the product, which is in many cases a part of a more complex product. One should know what type of contaminant and how much contaminant can harm the product performance and quality. It is important that the product or parts are cleaned to a cleanliness level better than the required cleanliness of the final product. From the difference the total acceptable contamination during processing can be determined. This information is used to select the right contamination control solutions at critical locations.

By a risk assessment the requirements for critical manufacturing locations can be deduced. The cleanliness requirements are the input for the selection of contamination control solutions. When the proper potential solution is selected the required control can be established and verified. Once the solutions are executed, the air and surface cleanliness are monitored to demonstrate that the manufacturing processes are in control.

In this paper references will be made to the relevant standards developed by the ISO Technical Committee 209 for Cleanrooms and associated controlled environments.

Product cleanliness

To express the cleanliness of a product, the concentration of contaminants on the outer surface is determined. Contaminants can be particles and/or chemicals. In this paper microbiological contamination and nano-size particles are not considered. However the general approach for these contaminants will be similar.[1]

For particles, the number concentration of particles larger than one or more specific sizes is used. For chemicals, the mass concentration per type of chemical is used. There are various general standards and application related standards and guidelines that can be used to express the surface cleanliness. Once the specific concentrations are known, the values for each standard can be calculated relatively easily. In this paper, ISO 14644-9:2012: Cleanrooms and associated controlled environments *Classification of surface cleanliness by particle concentration*[i] and ISO 14644-10:2013 *Classification of surface cleanliness by chemical concentration*[ii] are used. The starting point is the required product surface cleanliness after cleaning.

For surface cleanliness by particle concentration, the SCP cleanliness class number is designated as:

SCP Class *N* (D µm) where N is the SCP classification number and D is the considered particle size, in µm. The designation must also include the surface type measured, the surface area measured and the measurement method, for example (taken from ISO 14644-9:2012)

SCP Class 5 (0.5 µm): inner wall of bottle, surface area 200 cm^2; liquid dispersion – liquid particle counter

N is calculated from the following formula:

$$C_{SCP;D} = k\frac{10^N}{D}$$

Where

$C_{SCP;D}$ is the maximum permitted surface concentration in particles per m^2 of particle ≥ the considered particle size

N is the SCP classification number represented by the considered particle size

D is the considered particle size in µm

k is a constant which is 1 in µm

Therefore

$N = Log_{10}(C_{SCP;D}.D)$

For example for 1 particle ≥ 10 µm per cm^2 i.e. 10.000 particles ≥ 10 µm per m^2, the SCP classification number, *N*, is ISO

SCP $\log_{10}$ (10,000*10) = ISO SCP 5.

For surface concentration by chemical concentration, the SCC cleanliness class is designated by a classification number *Nscc* where *Nscc* is the common logarithm index of the surface concentration *Cscc* expressed in g/m^2. The SCC class number is only valid with a descriptor that includes the chemical substance or group of substances to which the class number applies. The format is ISO-SCC Class *N* (X) where X is the chemical substance or group of substances. The ISO SCC class is always a negative number. If *Cscc* is in g/m^2, the ISO SCC class is $\log_{10}$ *Cscc*, for example hydrocarbons at 1 ng per dm^2 or 10^{-7} g/m2 is ISO SCC Class –7 (hydrocarbon).

Contamination mechanisms

A clean surface can get contaminated by deposition or by contact transfer.

In air, particles larger than a few microns fall by gravitation, but in the meantime they are carried by the airflow. Turbulence transfers momentum to the particles. When a pocket of air passes a surface, particles can be deposited onto that surface if their mass is high enough. Small particles and particles with a high area/volume ratio will stay airborne. These particles are removed by the airflow. Particle deposition measurements show that most particles larger than 25 µm are not removed from a room effectively by airflow. The deposition of particles onto a surface depends on their concentration in air and their deposition velocity. If the airflow is near an electrostatic charged surface, deposition can be influenced by electrostatic forces.

Particles can also be transferred to a 'clean' surface by contact when it touches a contaminated surface. The transfer is determined by the difference in surface cleanliness, the transfer coefficient, which depends on the contact conditions, the contact area and the number of contacts. The transfer efficiency is somewhere between 2 and 20 %, being high on flexible surfaces and low on smooth hard surfaces. Contaminated surfaces will have been contaminated by particle deposition, often for a lengthy time of exposure, and/or by contact with dirty surfaces. Regular cleaning, controlling the Particle Deposition Rate (PDR) and avoiding unnecessary exposure of tools will help to control surface cleanliness.

Unwanted chemical substances can condense or adsorb onto surfaces. The deposition depends on concentration, type of chemical, surface condition and temperature. Such surfaces that are chemically unclean can transfer their chemical substances onto clean product surfaces by contact.

Contamination control solutions

To limit surface contamination the concentration of the contaminants of interest in the air should be sufficiently low and in control. The principles of the contamination control solution are isolation (box in box), limitation of generation of contaminants and prevention of transport of contaminants into a controlled environment. A controlled environment is cleaned by flushing with filtered air and by regular cleaning of all surfaces. A large controlled environment in which people can work is a cleanroom (see figure 1). The supply air is filtered with HEPA or ULPA filters[2] that are classified by the filter efficiency of the most penetrating particle size (MPPS).

The most common used ventilation system is dilution with non-unidirectional air flow. In the most critical cleanrooms or clean zones displacement by unidirectional air flow is applied. The performance of cleanrooms is classified by the concentration of airborne particles (≥ 0.1 to 5 µm) per m^3 in 3 states of occupancy: "as built", "at rest" and "operational". According to ISO 14644-1:2015 , a cleanroom can be classified for one or more particle sizes. The standard includes a normative table showing classes of air cleanliness by particle concentration for particle sizes between 0,1 and 5 µm. Low concentrations (<10 particles/m^3) have not been included in the table for sampling and statistical reasons. In the case of particles ≥ 5 µm the problem of particle losses in the sampling system sets the concentration limit even higher. A normative annex to the standard provides a table with the minimum number of sample locations required for a given room area. The average measured concentration must be within the class limit at all sample locations. The designation of airborne particle concentration for cleanrooms must include the ISO Class number, expressed as "ISO Class N", the occupancy state and the considered particle size(s). An example would be a cleanroom designated as ISO Class 6; operational; 1 µm. If somebody claims to have an ISO Class 6 cleanroom this information is simply not complete. Intermediate classes, e.g. 6.5, are permitted and a table for these is given in an informative annex to the standard.

The table of ISO Classes only covers particles up to a threshold size of 5 µm but larger particles can occur in cleanrooms. Particles larger than 5 µm are referred to as 'macroparticles' in the standard and are designated by an M-descriptor: ISO M (a;b); c, where a is the maximum permitted concentration of macroparticles, expressed as macroparticles per m^3, b is the equivalent diameter associated with the specified measuring method and c is the specified measuring method, e.g. LSAPC (light scattering airborne particle counter). Measurement methods for particles up to 25 µm are discussed in this standard. The standard gives the example of 29 ≥ 5 µm particles per m^3 which is of course the maximum concentration of 5 µm particles for Class 5 in the old ISO 14644-1:1999[iv] standard, now removed from the table of ISO Classes as explained above. This is now designated ISO M (29; 5 µm) LSAPC. Thus, for larger particles, the air cleanliness is in effect expressed as a concentration and not as a class.

The monitoring of the air cleanliness in critical locations is described in ISO 14644-2:2015.[v] In this standard air cleanliness will normally be monitored at critical locations and expressed as a concentration so that alert and alarm levels can be set.

For some applications the air cleanliness with respect to chemicals (previously called "airborne molecular contamination") is important. This is described in ISO 14644-8:2013.[vi] Airborne chemical concentration is

1. Micro-organisms can be associated with macro particles (particles > 5 µm). Nano-particles will not pass HEPA filters and can be generated by processes during operation.
2. HEPA High Efficiency Particulate Air (H13 and H14) and ULPA Ultra Low Penetration Air (U15-U17). 1X stands for 99.9..5 % efficiency for the MPPS (somewhere between 0.1 and 0.3 µm), where X is the number of 9's.

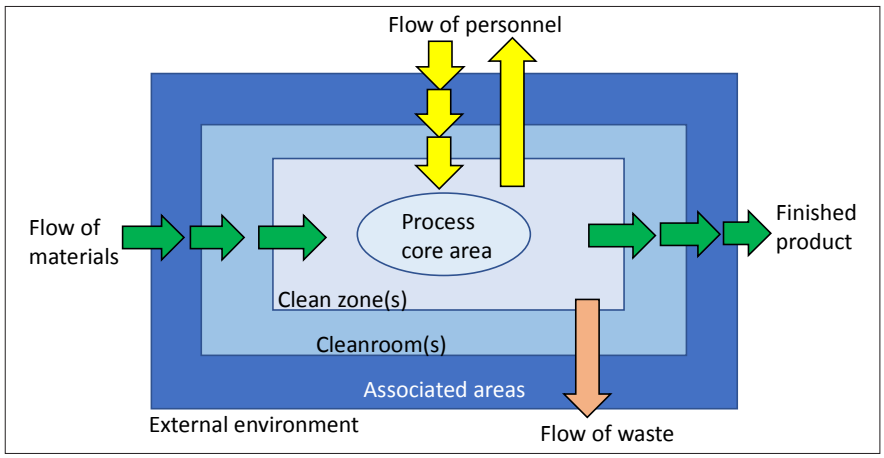

Figure 1: Schematic overview of a cleanroom and clean zone

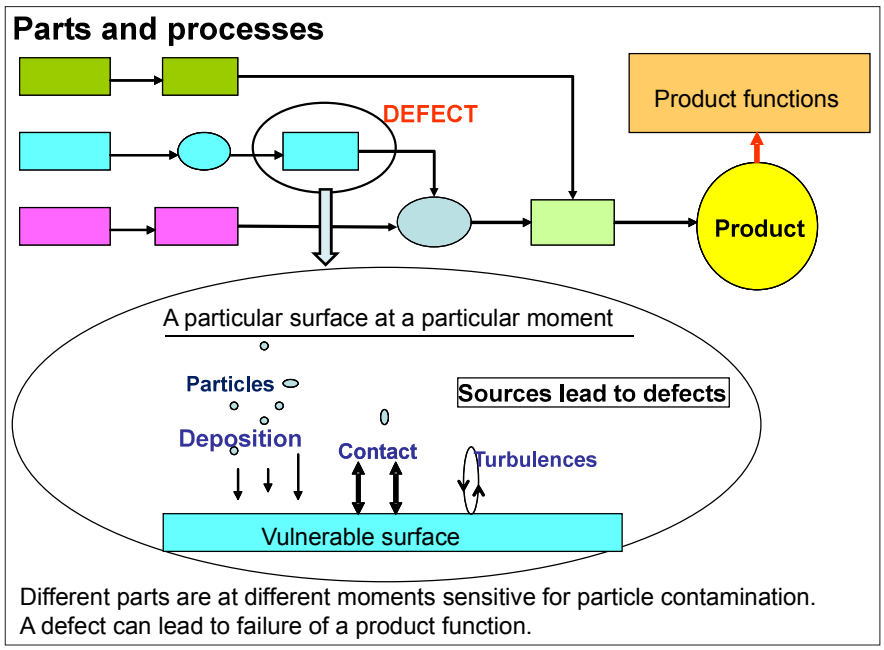

Figure 2: Schematic overview of a contamination of a critical product surface.

normally only specified and measured at critical locations since there is no one specific classification procedure for airborne chemical contamination in a cleanroom. Cleanliness levels can be achieved by avoiding substances that generate unwanted chemicals and by chemical filtration of the air.

To limit surface contamination by contact transfer the surface cleanliness of potential contact surfaces such as work benches, tools and equipment should be cleaned regularly to keep the surface cleanliness. Cleaning is carried out in accordance with the recently published ISO 14644-13.[vii] Acceptance criteria are agreed between customer and supplier and defined in accordance with ISO 14644-9:2012 for particles and ISO 14644-10:2013 for chemicals.

The surfaces under consideration will have been contaminated mainly by deposition of macroparticles. The PDR is determined by the concentration of the macroparticles in the air and their deposition velocity. A new standard ISO 14644-17,[vii] which will describe this, is under development (see also VCCN guideline 9[ix]). The deposition velocity increases with particle size or, more precisely, with mass and shape. The PDR of the larger particles is determined by the way the cleanroom is used or in other words by the quality of the operational procedures. Important operational procedures are garment use, entrance and exit procedures and cleaning. Cleaning of large surfaces is executed by professional cleanroom cleaners and of all working surfaces like tools by the operators. Good cleaning can only be achieved through proper training, cleaning methods and cleaning programs (ISO 14644-5[x]).

It is important to understand that particle deposition causes a build-up of contamination on surfaces. These then act as contamination sources in the neighbourhood of turbulent air flows and in contact with clean surfaces. The deposition of particles < 5 µm is an extremely low proportion of the airborne concentration and therefore, in most cases, it is the deposition of macro-particles and larger that is the real threat to product quality.

A cleanroom is expensive and consumes a lot of energy and so when possible it is important to look for alternative contamination control solutions. Storing a product in a clean box is a very effective way of keeping a product clean. Keeping people away from the product will protect it from the most important particle source and reduce contamination. By the use of separative devices, such as unidirectional airflow cabinets, glove boxes and mini-environments (see ISO 14644-7[xi]), people can be kept away from the vulnerable product. With this type of device, it should in theory be possible not to need a cleanroom, but in practice the cleanliness of the background is important during interventions and therefore a lesser classified cleanroom can be selected to control contamination of the separative device itself by the background.

Risk Assessment

A risk assessment starts with a description of the product's functions and the potential harm to each of them by contamination. This is the first step of a Failure Mode and Effect Analysis (FMEA) and is a good method for making a list of potential harms by contamination of the product. The vulnerable surfaces can be determined from the list of potential product failures or loss of quality.

For each of the vulnerable surfaces, the maximum allowable contamination of particles and/or chemicals should be determined bearing in mind that the lower these maximum quantities are set the more difficult they are to achieve. It should be noted that the starting point for the contamination level on a vulnerable surface is always the surface cleanliness level after the last cleaning. The net surface contamination is the difference between the initial surface cleanliness or contamination immediately after cleaning and the actual surface cleanliness or

contamination at a given time after that. During processing, the net surface contamination must not exceed the acceptable final net surface contamination. This process window, where the net surface contamination lies between the initial value and the final acceptable value is often referred to as the process latitude. The net surface contamination increases during processing due to deposition (PDR and time of exposure) and contact transfer (contacts and cleaning) but must always remain within the process latitude.

The next step is to analyse the manufacturing process and determine where each critical part surface is exposed to contamination by deposition and/or contact transfer (see figure 2).

At each critical location the latitude can be used to determine the limits for air cleanliness, surface cleanliness and deposition rate. There are no real formulae to set these limits, but it is possible to make realistic estimates. The set levels can be reached by clean operational procedures, cleanroom conditions and separative devices. The more the data, the better are the estimates.

The requirements for air cleanliness of particles from 0.1 up to 5 µm and PDR levels for particles from 5 to 500 µm at critical location can be derived from the risk assessment. The PDR level for the smaller particles is determined by the air cleanliness of particles ≥ 5 µm, but for particles ≥ 25 µm the impact of the cleanroom airflow and filtration system reduces and the impact of operational procedures increases. The PDR in combination with the cleaning program determines the surface cleanliness of all surfaces in the cleanroom or clean zone.

In the example given below some steps in the determination of cleanliness levels are demonstrated. This example is not essential for the subsequent sections on design, construction, start up and operation of the contamination control solution.

Example

As an example a product surface with an area of 20 cm^2 is taken. This product is most vulnerable for particles ≥ 50 µm, the acceptable number of ≥ 50 µm particles is 0 (zero). The acceptable number of 25 µm particles is 1. The acceptable number of clusters of particles ≥ 10 is 0 (zero). Since it is not possible to work with zero particles the requirement for the 'killer' particles is set at 0.2 particles ≥ 50 µm per product (1 particle in 5 products) as a starting point. The requirement for the smaller particles is set as 10 particles ≥ 10 µm per product. These requirements are listed in Table 1. For the three particle sizes the acceptable final number of particles per product is recalculated into a surface particle concentration and ISO SCP class.

The cleanliness level that is achieved after cleaning is given in SCP class and per product. The difference is the latitude per particle size. The contamination control solution should keep the contamination within this range.

The latitude is used to determine the requirements for the contamination control solution. For the observed process the latitude is 90 % from particle deposition and 10 % from contact transfer with a tool with contact area 1.5 cm^2. This is worked out in Table 2.

The number of particles that deposit on a product ND is determined by the PDR_D for particles ≥ D µm per dm^2 per hour, the product area A and the time of exposure $t_{exposure}$ in hours:

$$ND = PDR_D * A * t_{exposure}. \quad (1)$$

So the required PDR Level PDRL = $D*PDR_D = D*N_D/(A*t_{exposure})$. The lowest required level (PDRL is 64) is found for the larger particles. This PDRL can only be low with very good operational procedures. The PDRL for particles that stay airborne longer is much higher (640). Particles ≥ 25 µm can be removed partially by the cleanroom airflow and filtration system, but operational procedures are much more important.

In the second part of Table 2 the impact of contact transfer is calculated. The number of particles that can be transferred by contact is determined by the number of contacts n, the transfer efficiency e, the contact area $A_{contact}$ and its surface cleanliness SC_D:

$$N_D \text{ contact transfer} = n*e*A_{contact}*SC_D. \quad (2)$$

The net surface cleanliness is determined by the initial surface

Table 1: Calculation of surface cleanliness latitude with respect to particles

Product area 20 cm^2							
Particle size	Acceptable number of particles on product	Final acceptable concentration	Surface cleanliness level	Final SCP class	Initial SCP class	Initial number of particles on product	Latitude per product
10	10	5000	50,000	4.7	4.0	2.0	8.0
25	1	500	12,500	4.1	3.5	0.3	0.7
50	0.2	100	5,000	3.7	3.0	0.0	0.2

Table 2. Calculation of PDR and cleaning frequency contact surface (tool)

		90% by deposition			10% by contact transfer		
Particle size	Latitude per product	Latitude per product	PDR_D per dm^2/hr	PDRL per dm^2/hr	Latitude per product	Max concentration N_D per cm^2	Max $t_{exposure}$ in hours
10	8.0	6.4	64.0	640	1.6	5.3	8.3
25	0.7	0.6	6.0	149	0.1	0.5	8.3
50	0.2	0.1	1.3	64	0.03	0.11	8.2

Figure 3: The APMON deposition monitor monitors particle events 24/7

Figure 4: Technology of Sense MOSC UV surface cleanliness monitor

cleanliness (the initial cleanliness ISO SCP 3 for particles ≥50 µm is extrapolated from 1 µm) plus the contamination during exposure. This means that the tools slowly become dirtier and need to be cleaned when the particle concentration on the contact surface is too high. With this input the max time of exposure until the next cleaning can be calculated. In this example an operational time of 8 hours is calculated. In a cleanroom at rest there is no deposition of macroparticles.

The contamination control of particles ≥ 10 µm depends on the cleanroom installation and the number of air changes. There is an empirical relation between PDR_5 and C5:

$$PDR_5 \text{ (no./m}^2\text{/hour)} = 81.2 * C_5^{0.773} \quad (3)$$

where, C_5 is the airborne concentration of particles ≥ 5 µm per m^3.

In a cleanroom the PDR for particles ≥ 10 µm is proportional to the PDR for ≥ 25 µm particles. The PDR Level used in a cleanroom is the maximum $D*PDR_D$.

For the requirement of the contamination solution a PDRL of 150 per dm^2/hr or 15,000 per m^2/hr is selected.

$$PDRL = 5*PDR_5 \quad (4)$$

From equations 3 and 4 the concentration of airborne particle ≥ 5 µm per m^3 can be determined:

$$C_5 = (PDR_5 / 81.2)^{1/0.773} = (PDR_5 / 81.2)^{1.29} \quad (5)$$

PDRL is set at 15.000 per m^2/hr. Then PDR_5 = 3,000.

This leads to a particle concentration C_5 = 106 particles ≥ 5 µm per m^3.

The nearest cleanroom class limit ISO class 6, which is 290 particles ≥ 5 µm per m^3 (operational).

From experience a PDRL of 50 per dm^2 /hr for large particles, which are not removed by the cleanroom installation, can be achieved by: full cover garments, no less than 40 m^2 per person, cleaning all goods that come into the cleanroom and cleaning of all surfaces with an effective cleanroom cleaning method within 8 operational hours.

Measurement methods

Air cleanliness with respect to particle concentration is based on data acquired with a light scattering airborne particle counter. PDR is determined by measuring the surface cleanliness of a witness plate before and after exposure. In a real-time particle deposition monitor a sensor is used that counts the change of surface cleanliness on the sensor for every period of 5 or more minutes. For example the APMON of Technology of Sense shown in Figure 3 uses inclined glass plates that collect particles and measure the collected particles using a holographic imaging technique.

Chemical contamination can be measured directly with a spectroscopic instrument but in most cases the air is sampled in a sorption tube that can be analysed in various ways, mostly by gas chromatography. Methods to measure chemicals in air are described in ISO 14644-8.

Surface cleanliness is measured directly with a microscopic method or with optical measurement equipment that is developed for this purpose. For example to measure human contamination on surfaces the MOSC, the UV surface cleanliness monitor of Technology of Sense shown in Figure 4, can be used. Surfaces with complicated shapes can be measured indirectly by carrying out a reference cleaning and measuring the released particles in the cleaning liquid. Several methods are described in ISO 14644-9.

Chemical contamination on a surface can be measured directly on a small surface but in most cases the surface is cleaned with a solvent and the non-volatile residues are measured using methods of chemical analyses explained in ISO 14644-10.

When determining the requirements for a clean facility it is important to select the measurement methods that will be used for verification and monitoring. Ideally a monitoring plan is developed before construction or at least before start up.

Establish Control

To establish a clean controlled environment, a cleanroom or clean zone or a combination of the two can be used. In ISO 14644-4[xii] the subjects and parameters that need to be considered when designing and constructing a cleanroom are described. Within two years there will be a revised ISO 14644-4 standard that will prescribe the minimal set of requirements as a starting point for the establishment of a controlled environment. Cleanroom classification is based on air cleanliness with respect to particles. Chemical cleanliness and surface cleanliness are cleanliness attributes that can only be used at critical locations or in clean zones, but they cannot be used to classify a cleanroom.

To achieve a certain air cleanliness level with respect to chemical cleanliness the selection of construction materials is important. No materials emitting the forbidden chemicals should be used. For example no silicone kit can be used in a cleanroom for the coating of a product, since it decreases the adhesion.

When designing a cleanroom it is important to get an accurate estimate of the contamination sources (number of people and equipment), since this determines the amount of cleanroom air. In many cleanrooms the quantity of air is too high; this costs a lot of energy. Guidance on energy management will be given in the new ISO 14644-16.

When the clean facility is completed it should be verified against the required cleanliness attributes. The cleanroom classification can be verified in the "as built" and, after the equipment is installed, in the "at rest" state. When the pilot operations are executed, the cleanroom class in the "operational" occupancy state can be verified. Relevant people should be trained in how to operate and use the controlled environment. Then operations can start.

Process equipment

With respect to cleanliness, process equipment should be treated in a similar way to the clean facility. Moving parts will generate particles and airflow will transport these particles. An approach to quantify this is described in ISO 14644-14.[xiii] Material used in equipment can emit unwanted chemicals. The way these can be measured is described in ISO 14644-15.[xiv]

Demonstrate control

After start up, the clean facility will be used for the regular operation. To demonstrate that air cleanliness is under control, PDR and surface cleanliness should be monitored according to a monitoring plan. Depending on the results of the monitoring plan, the measurement frequency can be adjusted. If the levels of the required cleanliness attributes exceed action or alert levels during operation action has to be taken to correct this. In most cases the operational procedures should be improved. Cleaning methods and frequencies, garments, cleanroom surfaces, tools and equipment are most important factors to be addressed.

The changing procedure, the transfer of goods into the room and working methods should also be considered. Unnecessary surfaces such as unused furniture or equipment should be removed since they become particle sources when not cleaned frequently.

When determining the requirements for a clean facility it is important to select the measurement methods that will be used for verification and monitoring. Ideally a monitoring plan is developed before construction or at least before start up.

Conclusion

In the world of contamination control a new way of thinking is developing and within five years a new approach will be incorporated in the new ISO standards. The first important standards for cleanrooms are ISO 14644-1 and 2, published in December 2015.

If one develops a manufacturing process for a new product the first step is a risk assessment. The requirements that are determined are used to find the optimal contamination control solutions ranging from a local solution, like a product container or mini-environment to a controlled clean environment. In cleanrooms people are the main source of particles, so the way personnel enter and work should be considered before making any design. People not only generate and distribute small particles that can be removed in the airflow, but also larger particles that deposit on surfaces and can only be removed by cleaning. Therefore the cleaning program should be considered right from the beginning.

The way the contaminants of interest will be measured should be decided before or at least during the design process. Once the contamination control solution is established, a monitoring program is implemented to demonstrate control or when corrective actions need to be carried out. Process equipment needs a similar approach.

References

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Koos Agricola is an Applied Physicist and has worked in R & D at Océ Technologies, a Canon Company, since 1986 and part time at Technology of Sense since 2017. His responsibilities include contamination control in cleanrooms for the manufacture of critical parts. Koos is a member of ISO/TC 209, convenor of WG 14, secretary of WG 4 and technical expert in ISO/TC 209 WGs 3, 11, 12 and 13 as well as CEN/TC 243 WG 5. He is chairman of the ICCCS Education and Technical Committees and the CTCB-I and secretary of the VCCN and the ISCC 2018 steering committee.