Airborne particle deposition in cleanrooms: Calculation of product contamination and required cleanroom class

W Whyte[1], K Agricola[2] and M Derks[3]

[1] School of Engineering, University of Glasgow, UK; [2] VCCN, Dutch Contamination Control Society, Leusden, the Netherlands; [3] Lighthouse Benelux BV, Boven-Leeuwen, the Netherlands.

Abstract

This is the third and final article in a series that discusses the deposition of airborne particles onto critical surfaces in cleanrooms. This article explains a method for calculating the amount of particle or microbe-carrying particle deposition onto critical cleanroom surfaces, such as product, and a method for calculating the airborne particle cleanliness class, or airborne microbial concentration that is required to obtain a specified and acceptable amount of product contamination.

Introduction

Previous articles in this series

In the first article of this series, Whyte, Agricola and Derks (2015) reviewed the various mechanisms of surface deposition of particles in cleanrooms and concluded that the important mechanisms were gravitational settling, turbulent deposition, electrostatic attraction and, for particles less than about 0.5µm, Brownian diffusion. Experiments were carried out with particles ≥10µm which showed that over 80% of the deposition was by gravitational sedimentation.

In the second article, Whyte, Agricola and Derks (2016) described an investigation in a cleanroom into the relationship between the airborne particle concentration and particle deposition rate (PDR). These two quantities are related by the deposition velocity of particles through the air, which allows the PDR to be calculated from the airborne concentration, and vice versa. Most particle sampling methods in cleanrooms report the concentration of 'cumulative' counts, which includes all particles above a considered size. Deposition velocities were not previously known for a range of cumulative counts but these were obtained in our second article by experimental and theoretical investigations supplemented by previously-published results.

Particle deposition rate (PDR)

The PDR is obtained by measuring the number of particles that deposit over a standard time onto a standard surface area, and use of the following equation:

Equation 1

$$PDR_D = (c_F - c_I) / t$$

where, PDR_D is the particle deposition rate of particles of a size D, c_F is the final surface concentration, c_I is the initial surface concentration, and t is time of exposure.

The units of measurement of PDR used in our previous two articles were number/dm²/hour but airborne particle concentrations in cleanrooms are usually reported per m³ and, to simplify the calculations, the PDR units used in this article are mainly number/m²/s, or occasionally number/m²/hour.

An analogous expression that can be used with airborne microbe-carrying particles (MCPs) is the microbial deposition rate (MDR), which is calculated by use of the following equation:

Equation 2

$$MDR = \frac{n}{t}$$

Where, n is the number of MCPs deposited on a standard surface area

The MDR is determined by exposing a settle plate for several hours, incubating the plate, and counting the microbial colonies. The nutrient agar surface of the plate will be sterile and therefore the initial count need not be ascertained, as in Equation 1. The number of MCPs that deposit onto a standard area such as m², in a standard time such as one second, is then calculated to determine the MDR.

Relationship between PDR, airborne particle concentration, and deposition velocity

The relationship between the PDR and airborne particle concentration is given by the following equation:

Equation 3

$$PDR_D = c_D * v_D$$

Where, c_D = airborne concentration of particles of a size D µm, and v_D = deposition velocity of particles of a size D µm

If the PDR is known, the number of particles that will deposit onto a surface can be calculated by use of the following equation:

Equation 4

$$\text{Number of particles deposited} = PDR_D * a * t$$

Where, a = area of exposed surface, and t = time the surface is exposed to airborne contamination

If the surface area slopes at an angle of $x°$ to the horizontal, an 'effective horizontal area' may be used to produce a more accurate result. This is obtained by multiplying the horizontal surface area by cos $x°$.

By substituting the value of PDR_D given in Equation 3 into Equation 4, the following equation is obtained that allows the number of particles deposited onto a surface to be calculated from the airborne concentration.

Equation 5

$$\text{Number of particles deposited} = c_D * a * t * v_D$$

If MCPs are considered, a set of analogous equations to those given above can be used, where MDR is substituted for PDR, and MCPs for particles.

Cleanroom airborne cleanliness classifications

Classification according to the PDR
A cleanroom can be classified according to its PDR by the method given in the VCCN Guidelines 9 (2014). In these guidelines, the Particle Deposition Class (PDC) of a cleanroom is determined by the following equation.

Equation 6

$$\mathrm{PDC} = \log_{10}(\mathrm{PDR_D} * D)$$

Where, PDR_D is the maximum permitted PDR (number/m^2/h) of particles that are equal to, or larger than, the considered particle size, D (µm).

Classification according to airborne particle concentration
The airborne cleanliness of a cleanroom is classified by ISO 14644-1 in terms of the concentration of particle sizes in the range between ≥0.1µm and ≥5µm, and use of the following equation:

Equation 7

$$C_n = 10^N . \left(\frac{0.1}{D}\right)^{2.08}$$

Where, C_n is the maximum permitted concentration/m^3 of airborne particles that are equal to, and greater than, the considered particle size, *N* is the ISO class number, and *D* (µm) is the considered particle size.

Rewriting Equation 7 in terms of the cleanroom class (N) gives the following equation, which allows the ISO Class (N) to be calculated from a concentration of particles of a considered cumulative size.

Equation 8

$$N = \log\left[\frac{C_n}{\left(\frac{0.1}{D}\right)^{2.08}}\right]$$

Later in this article, a method is given to calculate the maximum ISO class required to ensure that airborne contamination of a product is not greater than a specified and acceptable amount. If the critical particle size that causes the contamination is within the normal range of particles used in ISO 14644-1 i.e. ≥0.1µm to ≥5µm, the maximum particle concentration can be calculated and the ISO class obtained by reference to the classification Table 1 given in ISO 14644-1. However, particles with cumulative counts greater than 5µm are not given in this table and therefore it was necessary to calculate the ISO class by use of Equation 8. However, it is not clear how accurate this calculation would be, and this was investigated.

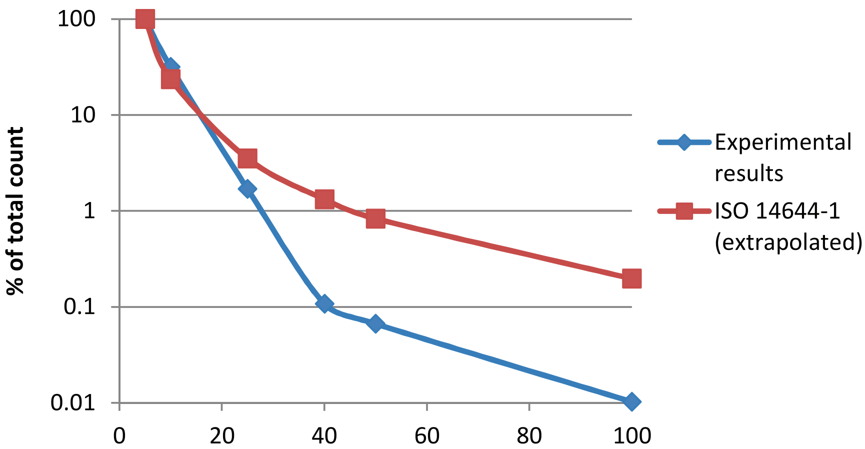

Figure 1: Airborne particle counts as a percentage of the total particle counts ≥5µm. ISO 14644-1 (extrapolated) is calculated using Equation 7.

Shown in Figure 1 are the concentrations of cumulative counts of different sizes of airborne particles obtained in the cleanroom experiments reported in the second article of this series (Whyte, Agricola and Derks, 2016) and given as a percentage of the total count of all particles ≥5µm. Also shown is an extrapolation of the particle size concentrations of ISO 14644-1 calculated by Equation 7. It can be seen that these diverge from the actual concentrations at about ≥20µm, and by about ≥40µm the concentration is about 10 times greater. Therefore, for more accurate calculations it is better not to use sizes above ≥20µm

Deposition velocity of particles

The deposition velocity of particles is their velocity through air towards a cleanroom surface. The deposition velocities of 'discrete' sizes of particles have been obtained both theoretically and experimentally by various researchers, and this information is discussed in our second article. However, the normal method of measuring particles in a cleanroom is by cumulative counts, where all particles above a considered particle size are measured, but the deposition velocity of cumulative counts have not been previously available. These were determined in our second article, and given in Table 1 in cm/s.

The cumulative deposition velocities given in Table 1 can be used in Equation 3 to calculate PDRs from knowledge of the cumulative particle concentration in the cleanroom air. However, investigations reported in our second article showed that to calculate the most accurate PDRs, the following restrictions should apply.

1. The calculations should only be applied to 'operational' conditions in a cleanroom i.e. during manufacturing, and not in 'at rest' conditions.
2. The calculation of PDRs for particles above about ≥30 µm should be avoided as the cumulative size distribution, and therefore the deposition velocity, is affected by variations in surface cleanliness and redispersion of particles by activity.
3. With the exception of particles ≥0.3µm, the deposition velocities given in Table 1 were obtained from observations in an ISO Class 8 room. However, it was found that the PDR increased as the particle concentration decreases. This was considered to be caused by lower particle concentrations being associated with higher air supply rates, where smaller particles would be quickly swept from the cleanroom with little time to deposit, but larger particles would still deposited by gravity. This effect was expected

Table 1: Deposition velocities of cumulative counts of particle sizes

Cumulative particle diameter	≥0.3µm	≥0.5µm	≥5µm	≥10µm	≥25µm	≥40µm	≥50µm	≥100µm
Deposition velocity (cm/s)	0.003	0.006	0.3	0.9	4.2	9.1	13	41

to increase as the average residence time of the air reduced. An increase in the turbulent intensity of the air was also thought to be a contributing factor. For a range of particles between about ≥5µm and ≥30µm, the deposition velocities would be expected to increase by about 1.7-fold if applied to an ISO Class 7 cleanroom, about 3-fold if applied to an ISO Class 6 cleanroom, and about 5-fold if applied to an ISO Class 5.

4. Particles ≥0.3µm or ≥0.5µm were expected to be less influenced by gravity, and the same deposition velocity applied over the range of cleanroom cleanliness classes.

The main, and usually only, source of MCPs in cleanroom air is personnel. Micro-organisms grow on the skin of personnel and, during activity, microbes are dispersed into the air on skin cells, or fragments of skin cells. MCPs have various shapes, and it is normal to consider particle movement in air and deposition onto surfaces, in terms of equivalent aerodynamic diameter, which is the diameter of a sphere of unit density that settles in air at the same rate as the particle being considered. The equivalent aerodynamic particle diameter is not the same as the equivalent optical particle diameter, the latter being used for the sizing of particles by optical particle counters. The average equivalent aerodynamic particle diameter of airborne MCPs has been reported by Noble et al (1963) and Whyte and Hejab (2007) to be about 12µm

The deposition velocity of the average size of airborne MCPs in different cleanliness conditions in cleanrooms has been recently investigated by Whyte and Eaton (2016), and reported in an article to be published soon. It was found that the deposition velocity increased as the cleanliness of the cleanroom increased, in a similar way to particles, and the results of the study are given in Table 2.

The purpose of this article is to explain calculation methods that can be used for the following purposes:

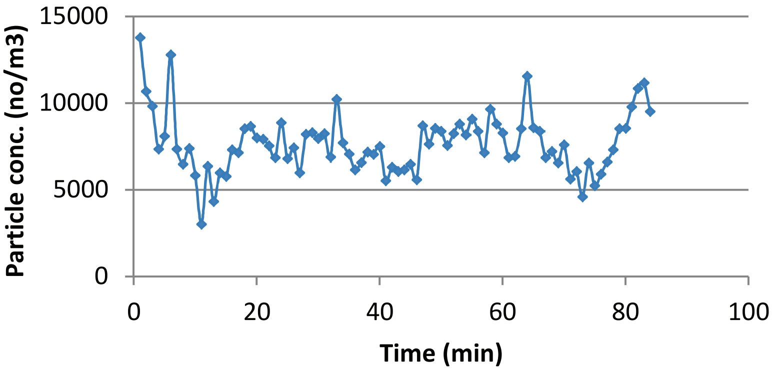

Figure 2: Concentration of particles ≥10µm at a sampling location over time

a. Establish the contamination rate of products manufactured in a cleanroom, when the PDR or airborne particle concentration is known;

b. Establish the maximum airborne cleanliness class, in terms of PDR or airborne particle concentration, for an acceptable and specified amount of product contamination;

c. Repeat (a) and (b) for MCPs.

Before discussing the methods used to carry out these three objectives, it is necessary to consider how the PDR or MDR, and airborne concentrations of particle and microbial contamination, should be sampled to ensure accurate results.

Measurement of airborne contamination in cleanrooms

It has been demonstrated that particle concentrations will vary about a cleanroom. In non-unidirectional airflow cleanrooms, Whyte et al (2010) have shown that the airborne particle concentration can vary about a cleanroom, depending on the performance of the air supply diffusers, temperature difference between supply and room temperature, position of the air extracts, and position of sources of contamination. Carr (1994) also reported that the particle concentrations in a unidirectional cleanroom will vary by up to 10-fold between locations. It is therefore important to ensure that sampling is carried out as close as possible to the product, or other critical surface, so as to reflect the actual airborne contamination adjacent to the surface.

Figure 2 shows the airborne concentration of particles ≥10µm measured during an experiment reported in the second article in this series. It can be seen that the airborne concentration varied by more than 10 times, and if particle deposition is to be accurately predicted, sampling must be carried out at the same time as products are exposed to deposition, and include periods of low and high activity. Sampling should also be carried out over a suitably long period of time or, if only short manufacturing times occur, by multiple sampling.

Calculation of the number of airborne particles deposited onto product

The number of airborne particles that may deposit onto a product, or another critical surface, can be calculated from knowledge of either the PDR or the airborne particle concentration. Both these methods are now considered by use of the following example.

A product has a horizontal upper-surface area of 2 cm^2 (0.0002m^2) that is exposed for 10 min (600s) to airborne contamination in a non-unidirectional ISO Class 8 cleanroom. The reliability of the product is known to be affected by contamination with particles greater than 10µm, and the likely number of these particles that will be deposited onto a product is required.

Table 2: Deposition velocities (cm/s) of MCPs in relation to airborne concentrations

Concentration of MCPs/m^3	0.1	0.5	1	5	10	50	100	200	500
Deposition velocity (cm/s)	3.55	2.04	1.61	0.92	0.73	0.42	0.33	0.26	0.19

Deposition calculated by means of the PDR: A witness plate, or instrument that measures PDR in real time, is placed adjacent to product, and sampling carried out over a period of several hours. The PDR of particles ≥10µm was found to be 610/dm²/h (16.9/m²/s). The number of particles deposited onto a single product can now be calculated by means of Equation 4.

Number of particles deposited onto a product = $PDR_D * a * t$ = 16.9 x 0.0002 x 600 = 2.03

This calculation shows that about 2 particles ≥10µm may be deposited on each product.

Deposition calculated by means of the airborne particle concentration: Product contamination can be calculated as follows:

1. The airborne concentration of the critical size of particles (≥10µm) is measured adjacent to the product. Sampling losses of particles into the airborne particle counter are minimised and, therefore, no sampling tube used. The air is sampled during normal manufacturing and measured over a sufficiently long period of time to obtain a reliable average concentration, which was 2500/m³.

2. The PDR is determined by Equation 3 from the airborne particle concentration. The cleanroom was known to be an ISO Class 8 and, therefore, the deposition velocity of particles ≥10µm, obtained from Table 1, is 0.9cm/s (0.009m/s).

   Therefore,
   PDR (no/m²/s) = $c_D * v_D$ =
   2500 x 0.009= 22.5

3. Knowing the surface area of product exposed to airborne contamination is 2 cm² (0.0002m²) and the time exposed is 10 min (600s), the product contamination can be determined by Equation 4,

   Number of particles deposited onto product = $PDR * a * t$ = 22.5 x 0.0002 x 600= 2.7

This method of calculation shows that each product will be contaminated by an average of 2.7 particles ≥10µm. This value is greater than obtained by the PDR method of calculation but a variation between the two methods should be expected, and caused by differences explained in our second article.

Calculation of maximum airborne particle class in a cleanroom

Cleanrooms are costly to build and run and, if a cleanroom is cleaner than required, the excessive supply of filtered air will be costly and wasteful of energy resources. If the cleanroom design produces insufficiently-clean conditions, then an unacceptable amount of product contamination may occur. It is, therefore, best that the cleanroom class is matched to a specified and acceptable amount of airborne product contamination, and the method to obtain this is now illustrated by an example.

It is considered that the critical size of particle that causes a malfunction when a product is contaminated is ≥10µm, and particle contamination should not be greater than one particle in a hundred products. The horizontal area of product exposed to deposition of particles is 2cm² (0.0002m²) and it is exposed for 10 minute (600s).

Calculation of the maximum PDR class: The PDR required for the specified level of product contamination (1 in 100 products) from particles ≥10µm can be calculated by use of the rewritten Equation 4:

$$PDR = \frac{\text{number of particles deposited per product}}{a*t}$$

$$= \frac{0.01}{0.0002*600} = 0.083/\text{m}^2/\text{s} = 300/\text{m}^2/\text{h}$$

The Particle Deposition Class (PDC) can then be found by reference to VCCN Guidelines 9 (2014) where it will be seen that, for particles ≥10µm, the upper limit of a PDC Class 4 cleanroom is 1000/m²/h. Therefore, a PDC of 4 is required.

Calculation of maximum airborne particle class requirement: The maximum airborne particle concentration for an acceptable amount of product contamination from particles ≥10µm can be obtained by firstly calculating the required PDR. This was found in the previous paragraph to be 0.083/m²/s. The required particle concentration is then calculated by using the deposition velocity of particles ≥10µm. The class of cleanroom is unknown and, as a first step in the calculation, an ISO Class 8 cleanroom is assumed, with a deposition velocity of airborne particles ≥10µm, as given in Table 1, of 0.9cm/s (0.009/m/s). Using the rewritten Equation 3, the maximum particle concentration can be calculated as follows:

Maximum airborne particle concentration

$$(\geq 10\mu\text{m}) = \frac{PDR}{v_D} = \frac{0.083}{0.009} = 9.2/\text{m}^3$$

A concentration of 9.2/m³ is, therefore, the maximum airborne concentration of particles ≥10µm that the cleanroom should achieve. However, it is normal practice to design a cleanroom in terms of an ISO 14644-1 class. The maximum concentration of airborne particles is defined in ISO 14644-1 for particles between ≥0.1 µm and ≥5µm and, had the critical size been in that range, reference to the classification Table 1 given in ISO 14644-1 would have given the maximum class of cleanroom that was required for the calculated particle concentration. However the particle size (≥10µm) is above that size range and it is therefore necessary to calculate the ISO Class by means of Equation 8 as follows:

$$N = \log\left[\frac{9.2}{\left(\frac{0.1}{10}\right)^{2.08}}\right] = 5.1$$

Therefore, the ISO class of cleanroom required to maintain an airborne contamination rate of 1 in 100 products is just over ISO Class 5. However, a second calculation step will improve the accuracy of the calculation, as the deposition velocity was assumed to apply to an ISO Class 8 cleanroom, whereas the required cleanroom was closer to Class 5. The deposition velocity used in the calculation was assumed to be 3 times greater i.e. 2.7cm/s (0.027m/s). The previous calculation is now repeated using a deposition velocity of 0.027m/s and the maximum airborne particle concentration found to be 3.1/m³, and the calculated ISO class 4.6. Owing to uncertainties associated with particle measurements, ISO 14644-1:2015 requires that ISO classes should be given in increments no greater than 0.5. Therefore, the maximum ISO Class is 5.

It has been previously shown that the concentrations of cumulative counts of different sizes of airborne particles found in cleanrooms diverge at about ≥20µm from the particle counts expected by extrapolation of the particle size and use of Equation 8. It is, therefore, better that the method of calculating the maximum ISO class is not used for cumulative particle sizes above 20µm.

Calculation of number of MCPs deposited

To calculate the surface contamination of products, or other critical surfaces, by microbe-carrying particles (MCPs), similar methods are used to those described for particles in the previous sections of this article. These methods are based on information obtained from either a) settle plates that determine the microbial deposition rate (MDR) or b) an airborne microbial sampler that ascertains the concentration of MCPs in the cleanroom air. The methods are illustrated by means of the example used in the previous two sections, in which a product with a horizontal surface area of 2 cm^2 (0.002m^2) is exposed to airborne deposition of MCPs for 10 minute (600s).

Calculation of microbial deposition onto product by use of settle plate counts

The method of calculating the product contamination from the deposition rate of MCPs onto settle plates has been previously discussed by Whyte (1986). This method is analogous to measuring the PDR by witness plates, and is likely to be a more accurate method than that involving the air concentration of MCPs obtained by microbial air samplers. Settle plates are Petri dishes that contain nutrient agar, and when exposed in a cleanroom, MCPs will deposit from the air onto their surface. Settle plates with a diameter of 90mm are commonly used, but 140mm diameter plates are more accurate for use in the low airborne concentrations found in cleanrooms; multiple settle plates are also more accurate. After sampling, the settle plates are incubated at a suitable temperature and time, so that MCPs grow into microbial colonies, which can be counted and used to find the number of MCPs that have deposited onto the settle plate in a given time. Settle plates should be laid out adjacent to product to ensure that the same deposition rate of MCPs is likely to occur on the settle plates as on product, and should be exposed for several hours. The calculation of microbial deposition is illustrated by an example.

A settle plate of 14cm diameter (area = 0.0154m^2) was laid out adjacent to product for 3 hours during manufacturing. To obtain an accurate result, the measurement was repeated several times and the number of MCPs deposited was found to average 3 per plate.

The microbial deposition rate (MDR) was calculated by means of Equation 2 as follows:

MDR (number /m^2/s) = count/m^2 $\div$ time surface exposed $= \frac{3}{0.0154} \div (3 * 3600) = 0.018$

This MDR is then used to calculate the product contamination. As the product has an exposed horizontal area of 2cm^2 (0.0002m^2) and MCPs have 10 minutes (600s) to deposit, the product contamination rate is as follows:

Number of MCPs deposited on a product = MDR*a*t = 0.018*0.0002*600 = 0.00216

This is equivalent to 1 in 463 products being contaminated by a MCP.

Calculation of MCP deposition onto product by means of microbial air sampler concentrations

The method of calculating product contamination from the airborne concentration of MCPs found by an airborne sampler has been described by Whyte and Eaton (2015), but that method used a single deposition velocity to cover all ventilation conditions in a cleanroom. In view of the recently obtained deposition velocities given in Table 2, the method should be modified to use different deposition velocities in different airborne cleanliness.

The measurement of the airborne concentration of MCPs by a microbial air sampler is analogous to using an airborne particle counter to measure the concentration of particles. However, microbial samplers measure all of the MCPs in the cleanroom air, and not the concen tration above a threshold size as measured by a particle counter. As all of the MCPs are counted, the required deposition velocity is the average deposition velocity of all airborne MCPs sampled. The deposition velocity is given in Table 2 over a range of ventilation conditions.

The example used to illustrate this method is again a product with an exposed surface area of 2cm^2 (0.0002m^2) and time of exposure of 10 min (600s). The product was manufactured in unidirectional airflow, and the average airborne concentration of MCPs found adjacent to the exposed product during manufacturing was 1/m^3. Table 2 was consulted and a deposition velocity of MCPs of 1.61cm/s (0.0161m/s) found. The average number of MCPs that might deposit onto a single product is calculated as follows:

Number of MCPs deposited on a product = $c * v_D * a * t$ = 1 * 0.0161 * 0.0002 * 600 = 1.9 x 10^{-3}

This is equivalent to a contamination rate of 1 in 518 products.

Calculation of the maximum MCPs deposition rate, or maximum airborne microbial concentration, for a specified product contamination rate

Methods have been outlined above for calculating the maximum airborne cleanliness class of cleanroom, according to ISO 14644-1, for an acceptable product contamination rate of particles. A similar method can be used with MCPs, and is demonstrated by use of the same manufactured product whose horizontal area is 2 cm^2 (0.0002m^2) and exposure time to airborne contamination is 10 minutes (600s). The acceptable microbial product contamination during manufacturing is set at 1 product in a 1000.

Calculation of maximum microbial deposition rate

The maximum MDR for a specified contamination rate of 1 in 1000 products can be calculated from the rewritten Equation 3.

Maximum MDR =

$$\frac{\text{number of MCPs deposited per product}}{a * t} = \frac{0.001}{0.0002 * 600} = 0.0083/\text{m}^2/\text{s}$$

This MDR can be used to obtain the required cleanliness of the cleanroom in terms of the maximum number of microbes deposited on a settle plate. If the settle plate used to sample the air is 14 cm diameter (surface area 0.0154/m^2) and exposed for 3 hours (3600s), the maximum microbial count on the settle plate is calculated as follows:

Maximum number of MCPs on a settle plate

$$= \text{MDR} * a * t = 0.0083 * 0.0154 * (3 * 3600) = 1.4$$

This result of 1.4 per settle plate is the number of MCPs that should not be exceeded if the specified product contamination rate of 1 in 1000 products is not to be exceeded.

Calculation of maximum airborne concentration of MCPs

The maximum concentration of airborne MCP in a cleanroom can be calculated in a similar way to that previously described for airborne particles, and illustrated by an example. To start the calculation, it is necessary have an estimate of the deposition velocity. As a first estimate, the cleanroom is assumed to be a non-UDAF type with an airborne concentration of 50/m³, and by consulting Table 2 it can be seen that the deposition velocity of the average size of MCPs at that airborne concentration is 0.42cm/s (0.0042m/s). The maximum MDR has been calculated in the previous section and, knowing it is 0.0083m²/s, the maximum MCP concentration is calculated as follows:

$$\text{Maximum MCP concentration} = \frac{\text{MDR}}{v_D} = \frac{0.0083}{0.0042} = 1.98/\text{m}^3$$

The calculated concentration of 1.98/m³ is lower than the concentration first estimated at the start of the calculation (50/m³) and the calculation should be repeated using a more accurate estimate of the deposition velocity. By consulting Table 2 it can be seen that the deposition velocity for an airborne concentration of 1.98/m³ should be closer to 1.5cm/s i.e. 0.015m/s. Using this deposition velocity, the maximum MCP concentration is re-calculated and found to be 0.55/m³.

$$\text{Maximum MCP concentration} = \frac{\text{MDR}}{v_D} = \frac{0.0083}{0.015} = 0.55/\text{m}^3$$

Discussion

This is the third and last article of a series that discusses the deposition of airborne particles onto critical surfaces in a cleanroom. The Introduction to this present article discusses the inter-relationship between the concentration of airborne contamination, the particle or microbial deposition rate (PDR or MDR), and the deposition velocity of particles and MCPs moving through air under the influence of deposition forces, which are mainly gravity. Equations are given that relate these variables and allow the number of airborne particles and MCPs that deposit onto critical surfaces to be calculated from knowledge of either the PDR or MDR, or the airborne concentration of either type of particle. Also given in the Introduction are equations that can be used to calculate the maximum airborne cleanliness class for either particle deposition (according to VCCN Guidelines 9) or airborne particle concentration (according to ISO 14644-1). These same equations can also be used to calculate the maximum number of MCPs that will deposit onto settle plates, or maximum concentration of MCPs measured by an airborne microbial sampler. The most accurate method of calculating the amount of deposition, or maximum airborne concentration, is by the PDR or MDR as this deposition closely simulates the actual deposition, and does not require the use of the deposition velocity.

To obtain the most accurate results from the equations given in the Introduction, the deposition rate and airborne concentration of contamination should be measured adjacent to the product, and over the time the product is open to airborne contamination, so that sampling accurately reflects the airborne concentration and deposition rate at the product.

The number of particles that deposit onto a product from cleanroom air can be calculated from the measurement of the PDR and use of Equation 4. Equation 4 also requires the minimum size of particle that causes contamination problems (the critical size), the surface area of product exposed to deposition, and time of exposure. Instruments have been available for some time to measure the PDR onto cleanroom surfaces such as silicon wafers, but it is only recently that relatively inexpensive and portable instruments have become available (Agricola, 2015 and 2016). However, where an instrument to measure PDR is not available, the airborne concentration of particles above the critical size can be measured by an airborne particle counter, and the PDR calculated by knowledge of its corresponding deposition velocity for cumulative counts.

Table 1 gives the deposition velocities of cumulative counts of a range of particle sizes. However, the deposition velocities may vary from those given in the table. It has been demonstrated in our second article (Whyte, Agricola and Derks, 2016) that to minimise variation, the calculations should be confined to operational conditions in the cleanroom, and the cumulative particle size should not exceed 30µm. Also, the deposition velocity should be modified for different ventilation conditions. The deposition velocities given in Table 1, with the exception of 0.3 and 0.5 µm particles, were obtained in ISO Class 8 conditions and should be increased by 1.7, 3 and 5 times for ISO Class 7, Class 6, and Class 5 conditions, respectively. The deposition velocity of particles ≥0.3µm and ≥0.5µm should be kept constant for different ISO Classes. Our previous article recommended that additional research is needed to obtain more accurate deposition velocities in different ventilation conditions, but irrespective of the outcome of these investigations, the present method will give useful results, especially as no method is presently available to calculate the expected rate of product contamination.

A method is also given in this article for calculating the maximum airborne class of cleanroom required for a specified level of product contamination. At present, when a cleanroom is designed, the required cleanliness class of a cleanroom is typically obtained by an informed guess. This often leads to cleanrooms that are much cleaner than needed, with unnecessarily-high capital and running costs. Occasionally, and more seriously, cleanrooms can be built that are not clean enough to avoid excessive airborne contamination. To avoid these problem, a method is required that matches an acceptable and specified contamination rate of product to a maximum cleanliness class of cleanroom. An example is given to show how this can be calculated for the PDC (according to VCCN 9), and airborne particle class (according to ISO 14644-1).

It is accepted that the calculation of the maximum ISO class for a cleanroom using the methods suggested in this article is unlikely to be exact, but should give a good indication of the type of cleanroom required e.g. non-unidirectional with a high or low air supply rate, unidirectional airflow, or the requirement of separative devices, and should be a considerable advance over the present method of using an informed guess and act as a useful additional aid.

Included in this article are methods for calculating the amount of product contamination by MCPs. The most accurate method of estimating product contamination will be obtained from the use of counts obtained from settle plates, as they directly measure the number of MCPs that will deposited onto a given surface area in a given time. Alternatively, the microbial airborne concentration can be measured and, by use of the appropriate deposition velocity given in Table 2, the amount of deposition calculated. This second method is unlikely to be as accurate, as the collection efficiency can vary between air samplers and can be low (Whyte et al, 2007) and an extra calculation is also required that is dependent on the accuracy of the deposition velocity. A method is also described that calculates the maximum deposition of MCPs on settle plates, or the airborne concentration, for a specified and acceptable amount of product contamination. These calculations should be a useful tool in contamination control in cleanrooms.

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W (Bill) Whyte, B.Sc. (microbiology), D.Sc. (mechanical engineering) and Honorary Research Fellow at Glasgow University, has been involved with cleanrooms for over 50 years. He has published over 140 reports and papers and written two major books on the subject. He is a founder and former chairman of the Scottish Society for Contamination Control and the Cleanroom Testing and Certification Board - International. He is a member of the BSI committee involved in the writing of cleanroom standards. He has extensive experience as an industrial consultant and running cleanroom courses.

Koos Agricola is an Applied Physicist and has worked in R & D at Océ Technologies, a Canon Company, since 1986. His responsibilities include contamination control in cleanrooms for the manufacture of critical parts. In his spare time, Koos assists Technology of Sense b.v. as a Contamination Control Specialist. Koos is secretary of the VCCN (Dutch Contamination Control Society), ICCCS (International Confederation of Contamination Control Societies) and ICEB (International Cleanroom Education Board) and a technical expert on ISO/TC 209 Working Groups 1, 3, 4, 11, 12 and 13 and CEN/TC243 Working Group 5. Koos is treasurer of the CTCB-I (Cleanroom Testing and Certification Board – International) and regularly teaches various cleanroom technology subjects.

Martin Derks is a skilled electronics engineer and has worked as calibration engineer and contamination control equipment expert for Philips Semiconductor where his role included responsibilities for cleanrooms, contamination control equipment for cleanrooms, maintenance and service. After 10 years as sales engineer for a manufacturer of particle counters, Martin became managing director for the European Headquarters of Lighthouse Worldwide Solutions. This company supplies contamination monitors for various cleanroom industries, like pharma, medical and semiconductor.