

# Calculation of airborne cleanliness and air supply rate for non-unidirectional airflow cleanrooms

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Equations have been recently derived by Whyte, Lenegan and Eaton for calculating the airborne concentration of particles and microbe-carrying particles in non-unidirectional airflow cleanrooms. These equations cover a variety of ventilation systems, and contain the variables of air supply rate, airborne dispersion rate of contamination from machinery and people, surface deposition of particles from the air, concentration of contamination in fresh make-up air, proportion of fresh air, and air filter efficiencies. The relative importance of these variables is investigated in this present research paper, with particular regard to the removal efficiency, location, and number of air filters. It was shown that air filters were important in ensuring low levels of contamination in cleanrooms but the types of filters specified in current cleanroom designs were very effective in ensuring a minimal contribution to the cleanroom's airborne contamination especially when a secondary filter is used in addition to a primary and terminal filter. The most important determinants of airborne contamination were the air supply rate and the dispersion rate of contamination within the cleanroom, with a lesser effect from deposition of airborne particles onto cleanroom surfaces. The information gathered confirmed the usefulness of the equation previously used by Whyte, Whyte, Eaton and Lenegan to calculate the air supply rate required for a specified concentration of airborne contamination.

**Key words:** Airborne particles, airborne micro-organisms, microbe-carrying particles, cleanrooms, cleanliness, air supply rate.

## Introduction

When designing a cleanroom to achieve a required airborne cleanliness standard or grade, such as specified in ISO 14644-1<sup>1</sup> or the European Union Guidelines to Good Manufacturing Practice (EU GMP)<sup>2</sup>, designers have difficulties deciding how much filtered air should be supplied to the cleanroom to achieve the correct airborne cleanliness requirement. Currently, this decision is based on experience and 'rules of thumb' and not normally by an analytical method. The consequence of this is that many cleanrooms have excessive air supply that is associated with high capital and running costs, and energy waste. Conversely, a low air supply may result in too high a concentration of contamination, and major remedial work to rectify the problem. It would be useful if an analytical method was available to assist in calculating the air supply rate, as well as making clear what variables affected the calculation, and their relative importance.

Prior to the start of manufacturing, personnel will enter an empty cleanroom that has a low airborne concentration of particles and microbe-carrying particles (MCPs). Personnel will then prepare for manufacturing and switch on machinery, and these activities will increase airborne contamination. When manufacturing starts and activity settles, the airborne contamination will fall a little to a fairly constant 'steady-state' condition, i.e. the operational condition. The airborne concentration in this condition determines the airborne contamination of products, and several researchers have derived equations to calculate it<sup>3-7</sup>. However, further investigations are still required into the effect of different designs of ventilation systems, and the method of calculating the reduction in the airborne contamination by the settling of particles from the air onto cleanroom surfaces, i.e. surface deposition. These variables have been incorporated into equations recently derived by Whyte, Lenegan and Eaton<sup>8</sup>.

Practical information on the values of the equation variables are required so that the equations can be used to design actual cleanrooms and these are discussed in this paper. Also investigated are the relative importance of the

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equation variables, and the possibility of simplifying the equations by disregarding unimportant variables.

There is also a need for a method to calculate the air volume supply rate in non-unidirectional airflow (non-UDAF) cleanrooms to ensure the maximum airborne contaminations specified in ISO 14644-1<sup>1</sup> and the EU GGMP<sup>2</sup> are not exceeded. This can be done by rewriting the equations that are used to calculate the airborne concentration of contamination so that the air supply rate can be obtained. The authors of this paper have published information on such a method<sup>9</sup> and the correctness of the approach was investigated.

## Equations used to calculate airborne cleanliness in a cleanroom

Equations have been derived by Whyte, Lenegan and Eaton<sup>8</sup> for calculating the airborne concentration of particles and MCPs in a cleanroom when the filtered air is supplied by a variety of designs of ventilation systems. These equations calculate the concentration in the steady-state condition, i.e. the operational state in non-UDAF cleanrooms and should not be used in UDAF systems where air cleanliness is dependent on the effectiveness of the UDAF, and not on dilution by air supply rate.

The deposition of particles and MCPs onto cleanroom surfaces has been investigated by Whyte, Agricola and Derks in a series of articles<sup>10-12</sup>, who suggest the following Equation 1 for calculating the particle deposition rate (PDR) onto cleanroom surfaces. This equation can be used to determine the reduction in the airborne concentration of contamination in a cleanroom owing to losses through surface deposition.

### Equation 1

$$PDR_D = C_D V_D A$$

Where,  $PDR_D$  is the particle deposition rate onto surfaces,  $C_D$  is the airborne concentration of particles of a size equal to or greater than  $D$ ,  $V_D$  is the deposition velocity of these particles through air, and  $A$  is the area of particle deposition. If surface deposition in all of a cleanroom is considered, then  $A$  can be assumed to be equivalent to the floor area.

Air filters are normally discussed in terms of their removal efficiency, which is usually given as a percentage. In this article, the proportion of airborne contamination that penetrates the filters is also used. These parameters are related as follows.

$$\text{Penetration proportion} = 1 - \{\text{removal efficiency (\%)} / 100\}$$

A typical cleanroom ventilation system will recirculate air from the cleanroom, add fresh make-up air, modify the temperature and humidity, filter the air, and supply it into the cleanroom. The airborne concentration of contamination in the supply air is likely to differ according to the type of ventilation system utilised, and equations have been derived that allow the concentration to be calculated for three basic designs of ventilation systems (along with minor design modifications). The

design of these ventilation systems and the derivation of the equations have been more fully described in a previous article<sup>8</sup> and are only briefly described in this article.

The symbols used in the equations are as follows.

$C$	= concentration of airborne contamination in a cleanroom (no./m <sup>3</sup> )
$C_F$	= concentration of airborne contamination in fresh make-up air (no./m <sup>3</sup> )
$C_R$	= concentration of airborne contamination in recirculated air (no./m <sup>3</sup> )
$Q_S$	= total air volume supply rate to cleanroom (m <sup>3</sup> /s)
$Q_F$	= air volume supply rate of fresh make-up air (m <sup>3</sup> /s)
$Q_R$	= air volume recirculated from cleanroom (m <sup>3</sup> /s)
$\eta_P$	= removal efficiency of primary air filter
$\eta_S$	= removal efficiency of secondary air filter
$\eta_T$	= removal efficiency of terminal air filter
$D_M$	= average dispersal rate of contamination from machinery (no./s)
$D_P$	= average dispersal rate of contamination from personnel (no./s)
$A$	= area of deposition of particles (m <sup>2</sup> )
$V_D$	= deposition velocity of particles through air of a size $D$ (m/s)

### Type 1: Standard recirculation loop

Make-up air is normally mixed with recirculated air before any filtration occurs and the mixed air passes through a primary filter, a secondary filter (where installed) and a terminal filter (see **Figure 1**). However, if the make-up air and recirculated air are filtered by the same efficiency of primary filters before they are mixed, the same equations can be used. The airborne concentration in a cleanroom can be ascertained by a previously derived Equation 2<sup>8</sup>.

### Equation 2

$$C = \frac{C_O Q_O (1 - \eta_P) (1 - \eta_S) (1 - \eta_T) + D_P + D_M}{Q_S + V_D A - Q_R (1 - \eta_P) (1 - \eta_S) (1 - \eta_T)}$$

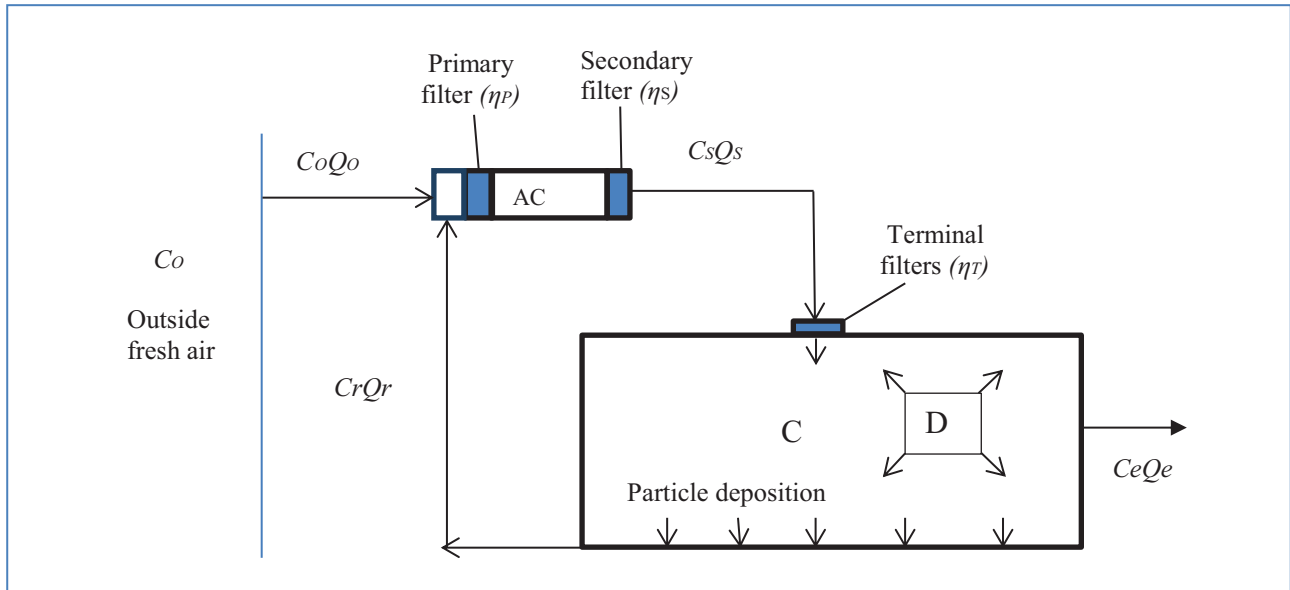
If a secondary filter is not installed, Equation 3 should be used.

### Equation 3

$$C = \frac{C_O Q_O (1 - \eta_P) (1 - \eta_T) + D_P + D_M}{Q_S + V_D A - Q_R (1 - \eta_P) (1 - \eta_T)}$$

### Type 2: Fresh air filtered before mixing with recirculated air

The make-up air is filtered by a primary filter, passes through an air conditioning plant, and then mixed with the recirculated air. The mixed air passes through a secondary filter (where installed), and through a terminal filter in the cleanroom ceiling. A variation of the design of this system is one where the air conditioning plant is located after the point of mixing of the fresh and recirculated air but the same quality of air passes through the same air filters. Equation 4 is applicable to both these designs.



**Figure 1.** Type 1: standard recirculation loop. AC = air conditioning plant, D = dispersion from machinery and personnel, air filters = ■.

#### Equation 4

$$C = \frac{C_o Q_o (1 - \eta_P) (1 - \eta_S) (1 - \eta_T) + D_P + D_M}{Q_S + V_D A - Q_R (1 - \eta_S) (1 - \eta_T)}$$

If a secondary filter is not installed, Equation 5 applies.

#### Equation 5

$$C = \frac{C_o Q_o (1 - \eta_P) (1 - \eta_T) + D_P + D_M}{Q_S + V_D A - Q_R (1 - \eta_T)}$$

#### Type 3: Recirculated air by-pass

Where there is a large demand for clean air, but the air conditioning requirement is relatively small, a proportion of the recirculated air is designed to by-pass the air conditioning plant and flow directly to the terminal filter. The make-up air will pass through all of the air filters, as will part of the recirculated air, but the other part of the recirculated air will only pass through the terminal filter. The concentration of airborne contamination in a cleanroom can be calculated by Equation 6.

#### Equation 6

$$C = \frac{C_o Q_o (1 - \eta_P) (1 - \eta_S) (1 - \eta_T) + D_P + D_M}{Q_S + V_D A - Q_{R,x} (1 - \eta_P) (1 - \eta_S) (1 - \eta_T) - Q_{R,y} (1 - \eta_T)}$$

Where,  $x$  is the proportion of the recirculated air that goes through the air conditioning plant, and  $y$  is the proportion that enters directly into the supply air duct.

If a secondary filter is not installed, Equation 7 is applicable.

#### Equation 7

$$C = \frac{C_o Q_o (1 - \eta_P) (1 - \eta_T) + D_P + D_M}{Q_S + V_D A - Q_{R,x} (1 - \eta_P) (1 - \eta_T) - Q_{R,y} (1 - \eta_T)}$$

#### Simplified equations

If air filters in the ventilation system have a sufficiently high removal efficiency to ensure that no airborne contamination is supplied to the cleanroom, i.e. the removal efficiency ( $\eta$ ) is 1, Equations 2 to 7 can all be simplified to the 'dilution and deposition' Equation 8.

#### Equation 8

$$C = \frac{D_P + D_M}{Q_S + V_D A}$$

If the reduction in the airborne concentration of the cleanroom by surface deposition has no practical importance, then Equation 9, which is known as the 'simple dilution' equation, can be used.

#### Equation 9

$$C = \frac{D_P + D_M}{Q_S}$$

### Constants and variables for use in the equations

To calculate the concentration of particles or MCPs in cleanroom air by means of the equations given in the previous section, the following information is required.

#### 1. The air volume supply rates of fresh, supply and recirculated air

The air volume supply rates of fresh ( $Q_o$ ), supply ( $Q_s$ ) and recirculated air ( $Q_r$ ) are obtained either from design data, or measurements made when the cleanroom is commissioned or tested.

#### 2. The concentrations of particles and MCPs in fresh make-up air

Compared to cleanroom air, the concentration of particles and MCPs in the outside fresh air is high. The outside

concentration can be measured externally at the cleanroom's site but if this is not possible, typical concentrations can be used. The authors have carried out sampling of outside air in rural and urban sites, when the weather was sunny, windy and rainy. All of the results were quite similar, and the highest results are given in **Table 1**. However, it is probable that even higher concentrations of particles and MCPs may be found. For use in this article (with a little rounding off), the particle concentrations were increased 10-fold, and the MCP concentrations doubled.

Contaminant	Concentrations/m <sup>3</sup> in outside fresh air	
	Experimental results	Concentrations used in calculations
Particles $\geq 0.5 \mu\text{m}$	$1.1 \times 10^7$	$10^8$
Particles $\geq 5 \mu\text{m}$	$6.5 \times 10^4$	$5 \times 10^5$
MCPs	45	100

### 3. The rate of particles emitted from machinery and equipment

MCPs are unlikely to be dispersed by machinery, and this possibility can generally be disregarded. Typical emission rates of particles have been reported<sup>9</sup>, and, generally speaking, they are lower than from personnel. Total emission rates from actual machines may be available from the manufacturer, or can be obtained experimentally by means of the method outlined in Annex B4 of ISO 14644-14<sup>13</sup>. This test method can be modified to include the particle emission from people operating the machinery to obtain the dispersion rate from all cleanroom sources.

### 4. Dispersion rate of particles and MCPs from cleanroom personnel

Information on the airborne dispersion rate of particles and MCPs from personnel exercising in a dispersion chamber (body box) has been reported in a series of articles by Whyte and his co-authors<sup>14-17</sup>, and by Reinmüller and Ljungqvist<sup>18-20</sup>.

Cleanroom clothing should act as an air filter against particles dispersed from the skin and inner clothing of people, and designed to fully cover a person and ensure that a minimum amount of airborne particles is dispersed into the air. It should also be made from a fabric that disperses few particles. The effectiveness of different designs of cleanroom garments and fabrics on the dispersion rate of particles<sup>14</sup> and MCPs<sup>15</sup> has been reported. The

ineffectiveness of gowns (smocks), which allow contamination to be dispersed from below the gown, has also been demonstrated<sup>16</sup>. Dispersion rates from a large group (55) of males and females have been determined<sup>17</sup> and if the information from all of these studies is combined, with emphasis placed on the study of 55 people, typical dispersion rates are obtained that are shown in the first two lines of results in **Table 2**. However, although these results are typical of cleanroom garments used in cleanrooms, better quality garments are available that give lower dispersion rates. Also, the results given in the second row of **Table 2** were obtained from personnel who wore their normal clothing under cleanroom coveralls. Discussion with Reinmüller and Ljungqvist, along with our unpublished observations, shows that more effective garments used with cleanroom undergarments can lower the dispersion rates to those given in the third row of results in **Table 2**.

The results in **Table 2** came from people exercising in a dispersal chamber, and this activity is likely to give a dispersion rate greater than found in a cleanroom. If an accurate estimate of the dispersion rate from the actual garments used in a cleanroom is required, then the rate from personnel working in a cleanroom can be measured in a cleanroom during simulated or actual manufacturing, and by use of the method suggested in Annex B4 of ISO 14644-14.

### 5. The deposition of particles and MCPs onto cleanroom surfaces

The PDR onto cleanroom surfaces can be calculated by means of Equation 3, which requires the deposition velocities through the air of different sizes of particles. Airborne particles are counted in cleanrooms as 'cumulative' counts, which includes all particles that are equal to, or greater than, a considered size. The deposition velocities of cumulative counts from a range of particle sizes are available<sup>11</sup> and a limited range of these values are given in **Table 3**.

The deposition velocities given in **Table 3** were obtained from observations in an ISO Class 8 cleanroom. For a range of particles between about  $\geq 5 \mu\text{m}$  and  $\geq 30 \mu\text{m}$ , the deposition velocities should be increased by about 1.7-fold when applied to an ISO Class 7 cleanroom, about 3-fold when applied to an ISO Class 6 cleanroom, and about 5-fold when applied to ISO Class 5. The same deposition velocity for small particles ( $\geq 0.3 \mu\text{m}$  or  $\geq 0.5 \mu\text{m}$ ) can be applied over a range of cleanroom classes.

Airborne MCPs are counted by microbial air samplers as a total number, and not as cumulative counts recorded by air particle counters. The deposition velocity that should be used with microbial counts is, therefore, the average

Type of cleanroom garments	Average dispersion rate per person (counts/s)		
	Particles		MCPs
	$\geq 0.5 \mu\text{m}$	$\geq 5.0 \mu\text{m}$	
Normal indoor clothing with, or without, gowns (smocks) over them	35,500	5500	40
Typical coveralls, hood and full length boots	17,000	600	3
Good quality coveralls, hood and full length boots	<1000	<100	<0.5



**Table 3.** Deposition velocities of a range of cumulative particle diameters.

Cumulative particle diameter	$\geq 0.3 \mu\text{m}$	$\geq 0.5 \mu\text{m}$	$\geq 5 \mu\text{m}$	$\geq 10 \mu\text{m}$	$\geq 25 \mu\text{m}$
Deposition velocity (cm/s)	0.003	0.006	0.3	0.9	4.2

velocity of all airborne MCPs. MCPs rarely occur in cleanroom air in unicellular form, but are found on skin or clothing detritus dispersed from personnel, and have been shown to have an average equivalent particle diameter in air of occupied rooms of about  $12 \mu\text{m}$ <sup>17,21</sup>. A recent investigation<sup>22</sup> has shown that the deposition velocity of MCPs is influenced, in a similar way to particles, by airborne conditions in a cleanroom, and the deposition velocity increases as the airborne concentration decreases. The deposition velocities of average MCP sizes have been published<sup>22</sup> and a limited range is shown in **Table 4**.

### 6. Removal efficiencies of air filters

High-efficiency air filters are classified by EN 1822:2009<sup>23</sup> and ISO 29463-1:2011<sup>24</sup>. The classification methods are similar and given in terms of the filter's most penetrating particle size (MPPS). The EN 1822:2009 classification system is used in this article. The MPPS varies according to the filter media, but in high-efficiency filters of the type used in cleanrooms, it is normally between about  $0.2 \mu\text{m}$  and  $0.5 \mu\text{m}$ <sup>24</sup>. In the case of particles larger than the MPPS, the removal efficiency will be greater but the actual efficiency value is unlikely to be known. In this case, and although an underestimate, it is reasonable to assume the same removal efficiency as obtained from the MPPS. However, in the case of MCPs, where the average particle size has been shown to be about  $12 \mu\text{m}$ <sup>17,21</sup> and the removal efficiency of filters has been shown to be about 1000 times greater than for the MPPS<sup>25</sup>, a 1000-fold increase in removal efficiency is assumed.

### Characteristics of cleanroom used as practical example

To investigate the changes in the concentration of particles  $\geq 0.5 \mu\text{m}$  and MCPs in a cleanroom caused by changes in the variables in Equations 2 to 9, a cleanroom with the following characteristics is investigated.

1. The cleanroom is non-UDAF with a floor area of 10 m x 10 m and height of 3 m, i.e.  $300 \text{ m}^3$  in volume. It is supplied with  $3.33 \text{ m}^3/\text{s}$  of high-efficiency particulate air-filtered air, which is equivalent to 40 air changes per hour. Of the room air supply, 10% is fresh make-up air. When a Type 3 ventilation system is studied, half the recirculated air by-passes the air conditioning plant.
2. Two people work in the cleanroom and wear cleanroom clothing that consists of a one-piece, woven-polyester coverall with hood and over-boots. The total dispersion

rate for two people is assumed to be  $34,000/\text{s}$  for airborne particles  $\geq 0.5 \mu\text{m}$ , and 6/s for MCPs.

3. A filling machine in the cleanroom disperses 500 particles  $\geq 0.5 \mu\text{m}/\text{s}$ .
4. The concentration of particles  $\geq 0.5 \mu\text{m}$  in the outside fresh air is assumed to be  $10^8/\text{m}^3$  and  $100/\text{m}^3$  for MCPs.
5. The deposition velocity of particles  $\geq 0.5 \mu\text{m}$  was assumed to be  $0.006 \text{ cm/s}$  ( $0.00006 \text{ m/s}$ ). The deposition velocity of MCPs depends on the airborne conditions in the cleanroom and it was necessary to carry out several iterations of the calculation of the airborne concentration in the cleanroom to determine an appropriate deposition velocity. This was finalised at  $1.5 \text{ cm/s}$  ( $0.015 \text{ m/s}$ ).
6. Using the EN 1822 classification, the primary filters were E10 bag filters with a removal efficiency of 0.85. The secondary filters (when installed) were H13 with a removal efficiency of 0.9995, and terminal filters were H14 with a removal efficiency of 0.99995. Other removal efficiencies were also investigated. The removal efficiency against MCPs was assumed to be 1000 times greater.

### Calculation of airborne concentration from different ventilation systems

Using the cleanroom properties given in the "Characteristics of cleanroom used as practical example" section, Equations 2 to 7 were used to calculate the concentration of airborne contamination in a cleanroom when air is supplied by the three different types of ventilation systems, and with and without an installed secondary filter. The results are given in **Table 5**, where it can be seen that the type of ventilation system made no practical difference to the airborne concentration in cleanrooms, although the omission of a secondary filter gave a slight increase in the particle concentration. It was also determined that the airborne concentration of MCPs did not vary according to the type of ventilation system, or from the addition of a secondary filter.

### Effect of equation variables on airborne concentrations in cleanrooms

The importance of the equation variables was found by calculating the different airborne particle concentrations in a cleanroom when the variables were changed. Equation 2 was used, which applies to the commonly used Type 1 ventilation system.

The concentration of airborne particles  $\geq 0.5 \mu\text{m}$  in the cleanroom whose characteristics are described in the

**Table 4.** Deposition velocities for different airborne concentrations of MCPs.

Concentration of MCPs/ $\text{m}^3$	0.1	0.5	1	5	10	50	100
Deposition velocity (cm/s)	3.55	2.04	1.61	0.92	0.73	0.42	0.33

Type of airborne contamination	Type of air ventilation system					
	Type 1: standard loop	Type 1: no secondary filter	Type 2: filtered fresh air	Type 2: no secondary filter	Type 3: recirculation by-pass	Type 3: no secondary filter
Particles $\geq 0.5 \mu\text{m}/\text{m}^3$	10,342	10,417	10,342	10,417	10,342	10,417
MCPs/ $\text{m}^3$	1.24	1.24	1.24	1.24	1.24	1.24

“Characteristics of cleanroom used as practical example” section was  $10,342/\text{m}^3$ . Each single equation variable was then given a value 10 times less, and 10 times greater, than its standard value, and the cleanroom concentrations calculated when the rest of the variables were kept constant. As the air volumes of fresh and recirculated air were interconnected and could not be individually investigated, proportions of 0.01 to 1 of the fresh make-up air of the total supply air were investigated.

The particle concentrations for each variable when their values were 10 times lower or higher, was divided by the reference value of  $10,342/\text{m}^3$  and the results shown in **Table 6**. These results are the number of times the cleanroom’s airborne concentration differs from that found in the standard set of characteristics.

**Table 6** shows that the most important variables are the air supply rate and dispersion rates from personnel and machinery, and a 10 times change of both these variables gives an almost directly proportional change in the airborne concentration of particles  $\geq 0.5 \mu\text{m}$  in the cleanroom. The floor area and deposition velocity gave a small change in the airborne concentration. The change in the removal efficiency of each filter made no difference, but a 10-fold change in efficiency was small in comparison to the range of filter removal efficiencies that are available. Filter efficiencies were, therefore, studied in more depth, and reported in the next section.

A similar study was also carried out into the effect of the equation variables on the cleanroom’s MCP concentration, and this gave similar values to those obtained from particles. Changes in the dispersion rates were in direct proportion to the airborne concentration in the cleanroom, although the changes in air volume did not have as great an effect as the particles (presumably owing to the effect of particle deposition). The effect of both the deposition velocity and floor area was greater than particles  $\geq 0.5 \mu\text{m}$ , e.g. a 10-fold increase in both deposition velocity and floor area gave a 0.26-fold decrease in MCP airborne concentration, and a 10-fold increase gave a 1.4-fold decrease in MCP airborne concentration. The other variables gave no change to the airborne concentration.

## Effect of filters and different ventilation systems on airborne concentrations

The effect of the number of air filters installed, their placement and removal efficiency was investigated using the three types of ventilation systems. Using Equations 2, 4 and 6, the airborne concentrations of particles  $\geq 0.5 \mu\text{m}$  in a cleanroom were calculated for combinations of the three filter efficiencies. The combinations of the filter removal efficiency that are investigated are given in the top part of **Table 7**, and progressively increase from zero removal efficiency in the left side of the table, to total removal efficiency in the right-hand side. Also investigated was the use, or not, of a secondary filter, with these results given in alternate rows in the bottom part of the table. It was assumed that the filtration system, i.e. filter, gasket and frame, had no leaks.

The concentration of airborne particles  $\geq 0.5 \mu\text{m}$  in a cleanroom that had no air filters installed was  $9.8 \times 10^7/\text{m}^3$ , and the importance of air filters is clearly shown by the concentration dropping to  $10,342/\text{m}^3$  when the removal efficiency of the filters was 1. This demonstrates that effective air filters can be responsible for reducing the cleanroom’s airborne concentration of particles  $\geq 0.5 \mu\text{m}$  by about 99.98%.

It can be seen in **Table 7** that when the filter efficiencies of the secondary and terminal filters are 0.9995/0.99995 (H13/H14), the concentration of particles  $\geq 0.5 \mu\text{m}$  in a cleanroom supplied by any of the three ventilation systems reaches a minimum of  $10,342/\text{m}^3$ , and any further increase in the filter’s removal efficiency gives no further reduction in the airborne concentration. Use of a less-efficient filter combination of 0.995/0.9995 (E12/H13) gives an increase of 3 to 6 particles/ $\text{m}^3$ , which is of no practical significance. However, to test for leaks, the filter system is challenged with a test aerosol of a size similar to the MPPS, and any penetration greater than 0.01% of particles through the filter is considered a leak. Therefore, to easily find a leak, without it being obscured by the normal passage of particles through undamaged filter media, the overall efficiency of filter should be equal or greater than 99.99%, i.e. a H14 filter.

It can be seen in **Table 7** that Type 1 and Type 2

Contamination control parameter	Proportion of fresh air supply	Total air supply $Q$	$\eta_P$	$\eta_S$	$\eta_T$	Concentration of fresh air $C_0$	Total dispersion $D_M + D_P$	Area of floor $A$	$V_D$
10-fold decrease	1.000	9.84	1.000	1.000	1.000	1.000	0.100	1.002	1.002
10-fold increase	1.000	0.100	1.000	1.000	1.000	1.000	10	0.984	0.984

Table 7. Airborne concentration of particles $\geq 0.5 \mu\text{m}$ in a cleanroom with respect to filter efficiencies and type of air ventilation system.							
Filter type	Filter efficiency according to EN 1822						
Primary	0	0	0.85	0.85	0.85	0.85	1
Secondary	0	0.85	0.95	0.995	0.9995	0.99995	1
Final	0	0.95	0.995	0.9995	0.99995	0.999995	1
Type of ventilation system							
Type of ventilation system	Concentration/ $\text{m}^3$ of particle $\geq 0.5 \mu\text{m}$ in cleanroom						
Type 1: standard loop	$9.8 \times 10^7$	85,785	10,716	10,345	10,342	10,342	10,342
Type 1: standard loop – no secondary filter	$9.8 \times 10^7$	533,402	17,840	11,091	10,417	10,349	10,342
Type 2: filtered fresh air	$9.8 \times 10^7$	85,785	10,718	10,345	10,342	10,342	10,342
Type 2: filtered fresh air – no secondary filter	$9.8 \times 10^7$	533,402	17,909	11,095	10,417	10,349	10,342
Type 3: recirculation air by-pass	$9.8 \times 10^7$	87,466	10,740	10,348	10,342	10,342	10,342
Type 3: recirculation air by-pass – no secondary filter	$9.8 \times 10^7$	533,402	17,874	11,093	10,417	10,349	10,342

ventilation systems give identical particle concentrations, even when the filter efficiency is low. The Type 3 system gives a higher concentration when the filter efficiency is low, as part of the recirculated air does not pass through either the primary and secondary filters. It is considered that the differences in particle concentrations between the three ventilation systems are of no practical significance. However, it can be seen in **Table 7** that the lack of a secondary filter has a more significant influence, especially when filter removal efficiencies are low.

Also investigated was the effect of the removal efficiency of filters on the airborne concentration of MCPs in the cleanroom. When no air filters are installed, the airborne concentration in the cleanroom was  $21/\text{m}^3$ . Any combination of primary/secondary/terminal filters given in **Table 7** gave an airborne concentration of  $1.24/\text{m}^3$ , and showed that a filter removal efficiency of 95% according to EN 1822 was sufficient to ensure an insignificant number of MCPs entered the cleanroom with the supply air.

### Calculation of airborne concentration by the simpler equations

The airborne concentrations in the cleanroom example were also calculated by use of the ‘deposition and dilution’ Equation 8, and the ‘simple dilution’ Equation 9. These results were compared to those obtained from Equation 3, which includes all the variables that influence airborne concentration. The filters investigated were a typical primary/secondary/terminal filter combination of

E10/H13/H14, with removal efficiencies of 0.85/0.9995/0.99995. The results in **Table 8** show that variations between the concentrations of particles  $\geq 0.5 \mu\text{m}$  calculated by each of these three approaches are of little practical importance. However, the ‘simple dilution’ Equation 8 gave a concentration that was a little higher and caused by lack of removal by surface deposition. Equation 9 took into account the deposition, and gave results identical to the equation with all variables included.

### Calculating the required air supply rates for a required airborne concentration of contamination in non-UDAF cleanrooms

Previous sections of this article contain equations for calculating the airborne concentration likely to be found in non-UDAF cleanrooms. However, it is also important to be able to ascertain the air supply rate for a required maximum concentration of airborne contamination, such as specified in ISO 14644-1<sup>1</sup> or the EU GGMP<sup>2</sup>.

It has been shown in this article that the main variables that affect the airborne concentration in non-UDAF cleanrooms are the air supply rate and the total rate of dispersion of contamination in the cleanroom. Air filters have a large effect, but this is negligible if the filters have high removal efficiencies that are typical of filters used in current cleanroom designs. If the other equation variables, including surface deposition, are considered to have no practical influence, the previously discussed ‘simple

Table 8. Comparison of airborne concentration calculated by different types of equations.			
Type of airborne contamination	Type 1: standard recirculation loop equation	Simple dilution equation	Simple dilution and deposition equation
Particles $\geq 0.5 \mu\text{m}/\text{m}^3$	10,342	10,360	10,342
MCPs/ $\text{m}^3$	1.24	1.80	1.24

dilution' Equation 9 can be used to calculate the airborne concentration of contamination. If this equation is rewritten in terms of the air supply volume ( $Q_S$ ), Equation 10 is obtained, which is the simple dilution equation previously used by Whyte, Whyte, Eaton and Lenegan<sup>9</sup> to calculate the air supply rate.

#### Equation 10

$$Q_S = \frac{D_T}{C}$$

Where,  $Q_S$  = total air supply volume rate ( $\text{m}^3/\text{s}$ ),  $D_T$  = total average particle dispersion rate from both personnel and machinery/s, and  $C$  = required airborne particle concentration ( $\text{number}/\text{m}^3$ ).

If the cleanroom design requires consideration of large particle sizes or MCPs then, to take account of surface deposition, the dilution and deposition Equation 11 should be used.

#### Equation 11

$$C = \frac{D_T}{Q} - V_D A$$

The calculation of the air supply rate by means of Equation 10 or 11 is based on the **average** dispersion rates from personnel. Therefore, when airborne particle concentrations are measured in an actual cleanroom, the **average** concentration of the air samples will be the same as the concentration calculated by Equations 10 or 11. This may be acceptable, but many cleanrooms users will expect the airborne concentration not to exceed a maximum value, such as required in the class limits of ISO 14644-1.

It is a scientific impossibility that all counts from air samples will never exceed a specified value, as the counts will conform to a statistical distribution where large counts will occasionally be found. However, it is possible to calculate an air supply volume that limits the occurrence of large counts to a specified, and low, frequency. This air supply is influenced by the spread (variation) of counts found in the cleanroom and, the greater the spread, the greater the air supply required to ensure the counts do not exceed the required concentration. The spread of the counts can be described by a coefficient of variation ( $C_V$ ) shown in Equation 12.

#### Equation 12

$$C_V = \sigma/\mu$$

Where,  $\sigma$  is the standard deviation of the counts and  $\mu$  is the mean of the counts.

Airborne sampling in cleanrooms by Whyte, Eaton and Lenegan<sup>9</sup> has shown that  $C_V$  can vary from about 0.5 to 2, with 1 being a common value. In addition, the Poisson distribution is often considered to represent the distribution of counts in a cleanroom and, as this distribution has a standard deviation equal to the count mean, this confirms the reasonableness of using a  $C_V$  equal to 1.

The required air supply is also dependent on the percentage of counts that the cleanroom user requires to be below the specified concentration. Shown in **Table 9** is the number of times ( $N_S$ ) the air supply should be increased above that calculated by Equation 11 when  $C_V$  is 1 and the percentage of counts below the specified concentration is either 95% or 99%.

If the air supplied to a non-unidirectional cleanroom does not perfectly mix with cleanroom air, there will be locations that receive less clean air than the average, and the airborne concentration of contamination will be higher than average. Extra air is required to compensate for these higher concentrations, and the air change effectiveness (ACE) index can be used to calculate the extra amount. A method of measurement and calculation of the ACE index ( $\epsilon$ ) is described in the American National Standards Institute/American Society of Heating and Air-Conditioning Engineers (ANSI/ASHRAE) standard 129-1999 (RA 2002)<sup>26</sup>. However, this method is best adopted for use in a cleanroom<sup>27</sup>, and if the recovery rate is measured at a critical location by means of the method given in ISO 14644-3 then, as the recovery rate is the same as the air change rate, the ACE index can be calculated from Equation 13.

#### Equation 13

$$\epsilon = \frac{\text{Air change rate measured at a critical location}}{\text{Average air change rate in cleanroom}}$$

If air mixing in the cleanroom is perfect, the ACE index will be 1 but if the test location receives more clean air than average (and hence the airborne concentration of contamination will be lower than average), the ACE index will be higher than 1. Locations that receive less clean air will have an ACE index lower than 1. When the ACE index is less than the room average i.e.  $<1$ , the air change rate may have to be increased to achieve the specified airborne concentration.

A method of obtaining the ACE index in non-UDAF cleanrooms has been previously described<sup>27</sup>, and it was shown that when effective air diffusers were fitted in non-UDAF cleanrooms, and the air extracts were at low level, ACE indexes close to 1 were common, and unlikely to be less than 0.7<sup>27,28</sup>. An ACE index of 0.7 can, therefore, be used to compensate for poor air mixing. However, in cleanrooms where good mixing is not obtained by effective air diffusers and low level extract, lower ACE

**Table 9.** Increase in air supply rates.

Percentage of counts below the particle limit	Ratio of standard deviation to mean ( $C_V$ )	Number of times increase in air supply rate ( $N_S$ )
95%	1	2.7
99%	1	3.5



values may be found and higher air supply rates are required to compensate.

If clean air devices are located in a non-UDAF cleanroom, they will reduce the airborne concentration of contamination in the cleanroom and hence the air supply rate requirement. Not all of the air from a clean air device mixes well with cleanroom air and the ventilation effectiveness coefficient ( $\beta$ ) gives the proportion of the supply air ( $Q_D$ ) coming from a clean air device that efficiently mixes with cleanroom air. Examples of values of  $\beta$  that have been reported<sup>2</sup> and are as follows.

- If a large unidirectional workstation is used, in which its intake air is drawn from the cleanroom and the supply air returns to the device's intake through the cleanroom,  $\beta$  may be about 0.5.
- If a large unidirectional airflow workstation is supplied with air from the main mechanical ventilation plant and its air exhaust is extracted through low level extracts around the cleanroom,  $\beta$  may be about 0.2.
- If the clean air devices are small and their supply air mixes well with room air before being drawn back into the device's intake, then a  $\beta$  of about 0.8 can be used.

The effect of (a) the additional dilution effect from clean air devices, (b) the ACE, and (c) an increase in air supply to ensure that measurements in the cleanroom will rarely exceed the specified concentration, can all be accounted for by Equation 14.

#### Equation 14

$$Q_S = \frac{D_T * N_S}{0.7 * C} - \beta Q_D$$

The surface deposition of particles has been shown to have little practical effect in reducing the airborne concentration of small particles such as  $\geq 0.5 \mu\text{m}$ , but if the particles are large or are MCPs, then for greater accuracy, the effect of surface deposition should be included, and Equation 15 used along with the appropriate deposition velocities given in **Tables 3** and **4**.

#### Equation 15

$$Q_S = \frac{D_T * N_S}{0.7 * C} - \beta Q_D - V_D A$$

A final requirement that may have to be considered is whether the air supply rate calculated by Equations 14 or 15 is sufficient to ensure that the 'clean up' requirements given in the EU GGMP, or a specified recovery rate or recovery time as described in ISO 14644-3 are likely to be achieved. This can be ascertained by a method described by Whyte, Lenegan and Eaton<sup>29</sup>, who report that when the ventilation effectiveness is taken into consideration, an air change rate of 26/hour should be sufficient for an EU GGMP Grade B cleanroom to ensure the correct 'clean up' requirements, and 13/hour for a Grade C cleanroom. However, the article<sup>29</sup> should be consulted for further information.

## Discussion

Equations have been derived by various researchers to calculate the airborne concentration of particles in non-UDAF cleanrooms in the operational state<sup>3-7</sup> but their equations usually apply to one type of ventilation system with a specific method of introducing fresh air into the recirculated air, and placement and number of air filters. However, a recent article written by Whyte, Lenegan and Eaton<sup>8</sup> describes equations that deal with various ventilation systems, and these equations are studied in this article.

The variables that might influence the airborne concentration of contamination in non-UDAF cleanrooms are the air supply rate, airborne dispersion rate of contamination from machinery and people, surface deposition of particles from air, concentration of airborne contamination in fresh make-up air, proportion of fresh air, and the removal efficiency, location and number of air filters. Actual values of some of these variables have not been previously available, and it has not been possible to use these equations for designing actual cleanrooms, or to investigate the relative importance of the variables. However, the principle author of this article has been involved in investigations into the surface deposition of contaminants<sup>10-12</sup>, and the airborne dispersion rate of particles and MCPs<sup>14-17</sup>, and the three authors of this article have investigated the concentration of particles and MCPs in outside air. Using this information, it is possible to calculate the airborne concentration likely to be found in actual cleanrooms, and the effect of the type of ventilation system and the equation variables.

The equations derived in a recent article<sup>8</sup> were used to calculate a cleanroom's airborne concentration of contamination when different ventilation systems are used, and it is shown in **Table 5** that when air filters of the type typically installed in cleanrooms were used, the type of ventilation plant made no practical difference to the airborne concentration in the cleanroom, although the installation of a secondary filter in addition to a primary and terminal filter, gave a noticeable reduction.

The importance of the variables in the equations was investigated by increasing or decreasing each variable by 10-fold and calculating the effect on the airborne concentration of particles  $\geq 0.5 \mu\text{m}$  in a cleanroom which used typical air filters. The most important variables were shown in **Table 6** to be the airborne dispersion rates from machinery and people, and the air supply volume, both giving a change in concentration that was almost in direct proportion to the change in the value of the variable. An increase in the outside concentration of airborne contamination, and the proportion of fresh make-up air in the air supply did not influence the cleanroom's concentration of contamination. The effect of surface deposition of particles  $\geq 0.5 \mu\text{m}$  was small and could be ignored. However, if larger particles and MCPs have to be considered, the amount of deposition should be included, and Equation 12 used.

Air filters of the type typically used in cleanrooms could reduce the airborne concentration of particles  $\geq 0.5 \mu\text{m}$  by 99.98% compared to an identical cleanroom

that did not use filters. It was shown in **Table 7** that there was no improvement in the particle concentration by any combination of air filters more efficient than the typical secondary/terminal filter combination of H13/H14. It was also demonstrated that a H13/H13 or E12/H13 combination gave a similar concentration of contamination in the cleanroom. However, the requirement to achieve a leak penetration of less than 0.01% during a particle test challenge meant that a H14 terminal filter would be required to ensure that leaks could be found without a problem of background contamination coming through undamaged filter media.

This study confirmed the correctness of our previous approach to calculating the air supply to a non-UDAF cleanroom by means of the dilution Equation 11<sup>9</sup>. However, to increase the accuracy of the calculation, the following should be included: (a) the additional air-cleaning effect of clean air devices, (b) an air change effectiveness index, and (c) an increase in the air supply to ensure that air samples taken in the cleanroom will rarely exceed the required concentration. To achieve this, Equation 13 should be used. When the concentration of larger particles and MCPs are calculated, the deposition effect should be included, and Equation 14 used. If the design of a cleanroom specifies a 'clean-up' requirement, or a similar recovery rate or recovery time, then the ability of the calculated air supply rate to achieve such requirements should be checked using the previously published information<sup>29</sup>.

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