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Decay of airborne contamination and ventilation effectiveness of cleanrooms

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Abstract

This article reports an investigation into the ability of the air supply in non-unidirectional cleanrooms to aid recovery from episodes of airborne contamination, and minimise airborne contamination at important locations. The ISO 14644-3 (2005) recovery test, which measures the rate of decay of test particles, was assessed and a reinterpretation of the test results suggested. This allowed air change effectiveness indexes to be calculated and used to evaluate the ventilation effectiveness of the cleanroom's air supply. Air change effectiveness indexes were measured in various designs of cleanrooms, and reasons for deviations in the value of the indexes investigated.

Key words: cleanrooms, airborne contamination, ventilation effectiveness, air change effectiveness index, decay rate

1 Introduction

Test gases, such as SH_6, N_2O and CO_2, are used in ventilated rooms to measure the room's air change rate. A burst of gas is introduced, mixed with room air, and the gas's decay rate is obtained, which is equal to the air change rate. The following equations give the relationship between decay and air change rate. The equations assume that no background test contamination enters the room in the supply air, or from adjacent areas.

$$C = C_I . e^{-Nt} \qquad \text{Eqn 1}$$

Where,
C = airborne concentration of test contamination after a given decay time,
C_I = initial airborne concentration of test contamination,
N = decay rate = air change rate,
t = decay time

Equation 1 can be rewritten as follows:

$$N = -\frac{1}{t}\ln\frac{C}{C_I} \qquad \text{Eqn 2}$$

Or, when logarithms to the base 10 are used,

$$N = -2.3\times\frac{1}{t}\log_{10}\left(\frac{C}{C_I}\right) \qquad \text{Eqn 3}$$

The measurement of decay rate is also used in cleanrooms to evaluate a cleanroom's ability to recover from episodes of airborne contamination. ISO 14644-3 suggests two decay tests for use in non-unidirectional airflow cleanrooms. These use small particles in preference to test gases, as particles more closely simulate cleanroom contamination, and most cleanrooms have a particle counter. Also, as particles in the supply air are efficiently removed by high efficiency filters, any possible complications caused by test contamination in the recirculated air can be avoided. Particles <1µm are used to ensure that surface deposition does not increase the decay rate.

The first test suggested in ISO 14644-3 measures the time for particles to decay to 1/100 of their initial concentration. The second test measures the 'cleanliness recovery rate', which is the decay rate (N) obtained from the following equation, known as Equation B12 in ISO 14644-3.

$$N = -2.3 \times \frac{1}{t} \log_{10} (\frac{C}{C_I})$$

A major problem with the cleanliness recovery test is that it does not provide a means of determining whether airborne contamination has been effectively removed from the test location.

Methods of assessing the effectiveness of the air supply method in removing airborne contaminants in ventilated rooms were first investigated in detail by Sandberg (1981), and the application of this work has led to indexes being developed that are based on the 'age' of the room air (Etheridge and Sandberg, 1996). The age of air that moves from the air supply inlet to a specific location within the room, is compared to the age of the air averaged over the entire room volume, and a ventilation effectiveness index obtained. The commonly-used Air Change Effectiveness (ACE) index is described in ANSI/ASHRAE Standard 129-1997 (RA 2002). However, this method differs from the ISO recovery rate method, and how an ACE index can be calculated from results gathered by the ISO recovery rate method is investigated in this paper.

There is little information available about ventilation effectiveness in cleanrooms. Cleanrooms differ from ordinary ventilated rooms, such as offices, by having much higher air change rates, different air inlet considerations, and an air movement between cleanrooms and adjacent areas, and therefore differences in ventilation effectiveness are to be expected. This expectation was investigated, along with reasons for deviations in ventilation effectiveness, so that more effective cleanroom designs could be obtained.

2 Experimental methods and cleanrooms studied

2.1 Air Change Effectiveness (ACE) Index

As discussed above, Equation B12 is used in ISO 14644-3 to calculate the decay rate of airborne test contamination in a cleanroom. This equation is identical to Equation 3, and therefore the decay rate measured by the ISO 14644-3 test method is the same as the air change rate at the measuring location. This information is not given ISO 14644-3, or that the measurement units of the test results are air changes per unit of time. If the air change rate at the measuring location is compared to the average air change rate in the whole cleanroom, an ACE Index can be calculated as follows:

$$\text{ACE} = \frac{\text{air change rate at a test location}}{\text{average air change rate in the cleanroom}} \qquad \text{Eqn 4}$$

Although this method of obtaining an ACE index differs from the method described in ANSI/ASHRAE Standard 129-1997 (RA 2002), both methods give the same index. A mathematical proof of this is given in the Annex.

The 'air change rate at a test location' required in Equation 4, which is also be known as 'local air change rate', is determined by measuring the decay rate of small test particles by using the method described in the next section 2.2. The 'average air change rate in the cleanroom' is obtained by measuring the air supply rate to the cleanroom and dividing the result by the room's volume. The air supply rate can be measured by instruments such as a Pitot static tube, or an airflow measuring hood. However, inaccurate instruments and inappropriate methods of use, may give incorrect results. An alternative method of obtaining the overall air change rate is to measure the decay of particle contamination in all of the room's exhaust pathways. This method has the advantage that the same type of measurement is used for both the air change rate at a location, and overall. The results from the exhaust pathways should be volume-weighed to take account of the different air volumes and concentrations passing through each exhaust. However, many cleanrooms have (a) multiple exhaust pathways that include exhaust grilles, door gaps and pressure-relieve dampers, (b) a positive (or negative) pressure with respect to adjacent areas that allows air to flow out (or in) through gaps in walls and ceilings, and (c) designs that require air to flow in and out of the room. These attributes increase the complexities of measuring all the air pathways, and make it difficult to use an exhaust-based method in many cleanrooms. The experiments reported in this article employed instruments to measure the air volume rate.

If the air within a cleanroom is perfectly mixed, the ACE index will have a value of 1 at all points in the cleanroom, and an even concentration of airborne contamination across the room. If the ACE index is lower than 1, less clean air than the average will have reached the test location and the particle concentration will be higher than the average. If the ACE index is greater than 1, more clean air than the average will have reached the test location, and the particle concentration will be lower than average.

2.2 Measurement of decay rate, air change rate, and ACE index

A few seconds burst from a single Laskin nozzle, fed with Shell Ondina EL oil, was used to introduce test particles into the cleanroom air. The count median diameter of particles produced by a Laskin nozzle is about 0.25µm, the mass median diameter about 0.71µm, and the geometric standard deviation about 1.5µm. These measurements vary a little, depending on the air pressure used, and fluids nebulised (Hinds, et al, 1983).

In the first set of experiments reported in section 3.1, the air supply was switched off and particles were thoroughly mixed with room air using a small fan. The air supply was then switched on, and the air flow pattern re-established. In the second set of experiments reported in section 3.2, test particles were introduced when the air conditioning plant was running.

ISO 14644-3 suggests that particles <1µm should be measured in the recovery tests, and the recovery test suggested in the EU GGMP (2008) for testing pharmaceutical cleanrooms requires particles ≥0.5µm to be measured. Therefore, the decay of particles ≥0.5 µm was measured by a Climet CI-500 airborne particle counter, with a sampling rate of 28.3l/min (1ft^3/min).

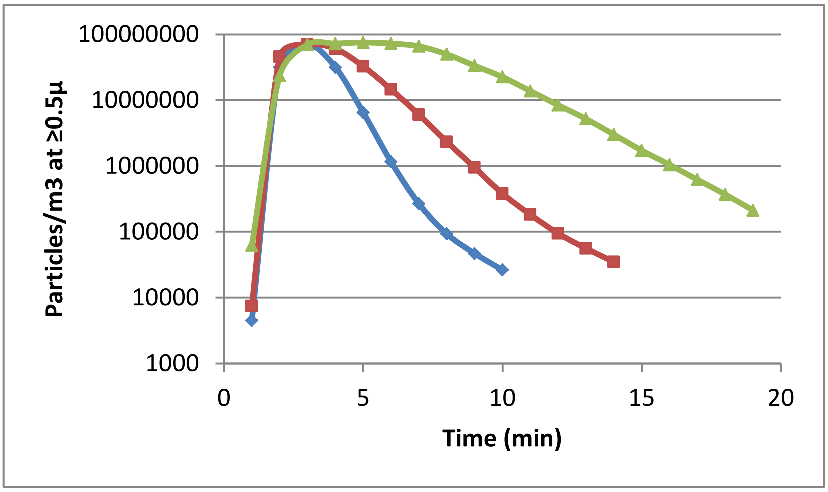

Figure 1 Decay of test particles ≥0.5µm in three cleanrooms with different air change rates

Shown in Figure 1 are examples of plots of the rise and fall of test particles introduced into three cleanrooms when the air conditioning plant was continuously running. The decay of particles in a cleanroom with an air change rate of 31/h is shown in the top-most graph, and that of 52 and 95 air changes per hour are shown in the middle and lowest-positioned plots, respectively. It should be noted that the Y axis has a logarithmic scale.

Figure 1 shows that prior to the introduction of particles, the airborne concentration is above zero, reflecting the dispersion of particles from people carrying out the experiments. There is then a steep rise in concentration caused by the introduction of test particles, with a maximum particle concentration of almost

$10^8/m^3$. This high concentration is useful, as it allows the test particles to mix with room air for several minutes before it drops to a level where accurate readings can be taken.

Care must be taken to avoid optical coincidence losses in the particle counter. When the particle concentration is high, the light scattered by two or more particles in the sensor's light beam may be interpreted as a single larger particle, and a lower count is registered. ISO 21501-4 (2007) requires the particle concentration to be established where the coincidence error is greater than 10%. In the case of the Climet CI-500 this is 2.83 $x10^7/m^3$ and, during these experiments, the airborne concentration was required to drop below this value before measurements were made.

After a mixing and settling-down period, the particle concentration decays in an exponential manner, as confirmed by a straight line. The initial and final concentrations were taken from this straight line, as the exponential decay indicated that good air mixing had occurred, the air pattern had been re-established, coincidence losses were not evident, and the decay rate at low particle concentrations was not influenced by particles dispersed by people.

The air supply rate to the cleanrooms was determined by use of an air volume measurement hood (TSI Pro-Hood) that had been recently calibrated. The volume of the cleanroom was measured, and the overall average air change rate of the room calculated. The ACE index was then calculated by means of Equation 4.

2.3 Types of cleanrooms studied

2.3.1 ACE index with respect to air supply diffuser

This experiment was carried out in a cleanroom that was the subject of a previous publication (Whyte et al, 2011) where the cleanroom is fully described. It was a non-unidirectional airflow type with a 7m × 4.6m floor area and a ceiling height of 2.76 m. The cleanroom was a positive-pressure type, and in these experiments the HEPA-filtered air supply rate was $0.37m^3/s$, which was equivalent to an air change rate of 15 per hour. The temperature difference between the supply air and room air was set at zero. The particle decay was measured at three locations in the cleanroom that were 1m from the floor, and below the air supply inlet, above the table, and between the table and the air extract grille.

2.3.2 ACE index in various designs of cleanrooms

Twenty-three non-unidirectional airflow cleanrooms were studied that can be divided into three different types by their air movement control between the cleanroom and adjacent areas. The three types were as follows.

a) Eleven of the cleanrooms were a positive-pressure type, where more air was supplied than extracted to ensure an outward flow of air, and a minimum of outside contamination entered the room. These are normally the cleanest type in a suite of non-unidirectional airflow cleanrooms. The air movement control method is shown in Figure 2, although there were variations in the size of room, the number and size of doors, and the number and placement of supply and extracts grilles. All these cleanrooms were supplied with HEPA filtered air from 4-way diffusers, and room air was extracted at low level. The air change rate per hour in the cleanrooms varied from 25 to 73.

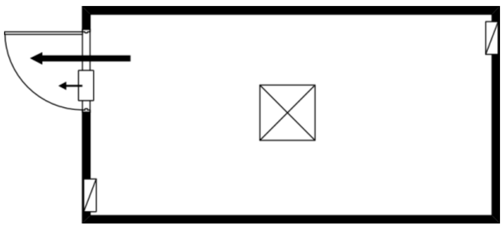

Figure 2 Air movement control in positive-pressure cleanrooms

☒ Diffuser ▧ Extract ⬅ Air Direction ▯→ Bypass Damper or Grille

b) Five of the cleanrooms were cascade types that are typically used in (a) preparation of materials, (b) gowning, and (c) material-transfer. Clean air was supplied by 4-way ceiling diffusers and extracted at low level. The air change rate per hour in the cleanrooms varied from 21 to 68. Air also cascades through these rooms, from an adjacent area that is normally cleaner than the outer less-clean area, such as a corridor. Figure 3 shows the method of air movement control.

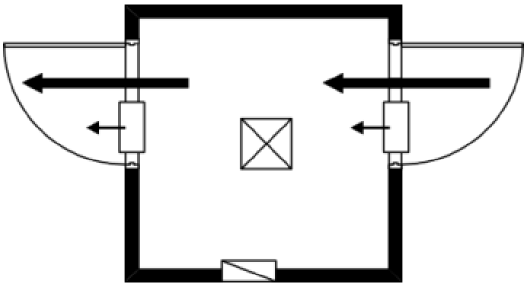

Figure 3 Air movement control in cascade-type cleanrooms

c) Seven negative-pressure cleanrooms were studied. These types of cleanrooms are used to minimise potentially-harmful contamination generated in the cleanroom escaping into adjacent areas, and the typical air movement control method is shown in Figure 4. More air is extracted from the room than supplied, with the balance of the air entering the cleanroom through door grilles and cracks round the doors.

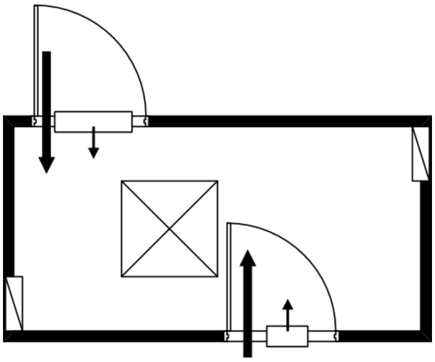

Figure 4 Air movement control in negative-pressure cleanrooms

The measurement of the ACE index was carried out in the three types of cleanrooms in the ‘at rest’ condition i.e. no machines were running and only test personnel present. All decay measurements were measured in the middle of the room at working height i.e. 1m from the floor. No clean air devices, such as unidirectional airflow workstations or isolators were switched on, so as to ensure there was no additional decay of particles.

3. Results

3.1 ACE index with respect to air supply diffuser

The resultant airflow pattern and associated air velocities, when no air supply diffusers were fitted, has been previously reported (Whyte et al, 2011). As shown in Figure 5, there was a pronounced downward flow of air under the air inlet. The velocities are given at the position of the arrows and obtained by turning the anemometer towards the direction of the airflow. The lengths of the arrows are not in proportion to the velocity as their range of values was too large to be shown in Figure 5.

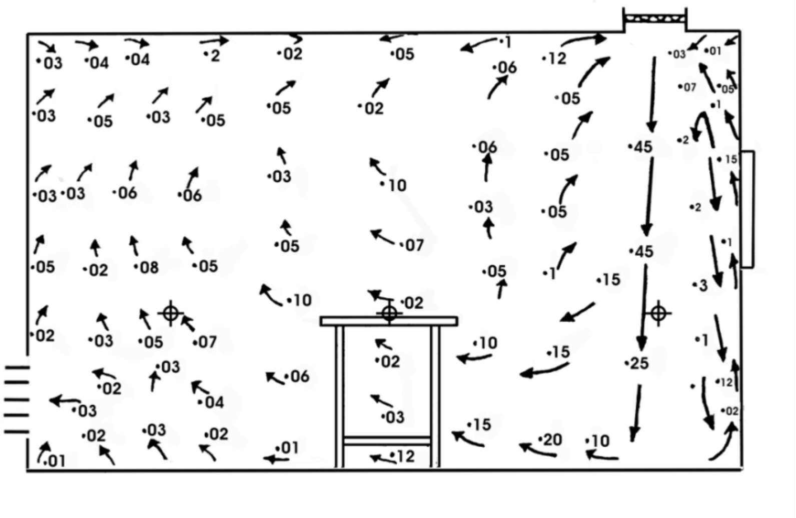

Figure 5 Airflow in a cleanroom with no diffuser at the inlet. ⌖= measuring location. Velocities given as m/s.

The ACE index below the air supply inlet was 1.8, above the table 0.87, and between the table and the air extract grille 0.68. These results show that under the air supply inlet, 1.8 times more clean air reached the test location than the room average. The experiments were repeated with 4-way diffusers fitted to the air inlets, and these gave good air mixing, as evidenced by the following ACE indexes: below the air inlet, 1.09; above the table, 1.04; between table and the air extract grille, 1.02.

3.2 ACE index in various designs of cleanrooms

3.2.1 Positive-pressure cleanrooms

Given in Table 1 are (a) average air change rates in the cleanrooms calculated from the room's air supply rate and volume, (b) local air change rates determined at the measuring location by the decay rate, and (c) ACE indexes.

Table 1 ACE index in positive-pressure cleanrooms. AC/h = air changes per hour

AC/h from air supply	25	26	28	29	29	30	30	34	43	47	73
AC/h measured by decay	26.7	26.1	35.7	29.0	24.0	20.5	30.9	22.7	41.8	37.6	67.8
ACE index	1.07	1.00	1.28	1.00	0.83	0.68	1.03	0.67	0.97	0.80	0.93

The mean value of the ACE index was 0.93, with a range of values between 0.67 and 1.28. The standard deviation was 0.18. There were two cleanrooms found to have an ACE index below 0.7. One was reinvestigated and the low index was considered to be caused by obstructions from large items of equipment. It was not possible to reinvestigate the other cleanroom.

3.2.2 Air cascade-type cleanrooms

Given in Table 2 are the average air change rates, local air change rates, and ACE indexes found in cascade-type cleanrooms. The mean value of the ACE index in these cleanrooms was 1.27, with a range of values between 0.90 and 1.82.

Table 2 ACE index found in cascade-type cleanrooms. AC/h = air changes per hour

AC/h from air supply	21	24	24	30	68
AC/h measured by decay	19	23	32.4	54.6	88.9
ACE index	0.9	0.97	1.35	1.82	1.30

3.2.3 Negative-pressure cleanrooms

Given in Table 3 are the average air change rates, local air change rates, and ACE indexes. The ACE indexes in Table 3 are calculated from the overall air supply rate to the rooms and not the air extract rate. The mean value of the ACE index was 1.66, with a range of values between 1.13 and 2.2

Table 3 ACE index in negative-pressure cleanrooms. AC/h = air changes per hour

AC/h- from air supply	22.5	31	34	34	37	37	38
AC/h measured by decay	25.5	56.4	56.3	75.4	50.7	56.2	64.0
ACE index	1.13	1.82	1.66	2.2	1.37	1.52	1.7

The ACE indexes in negative-pressure cleanrooms were further studied in two of the rooms. The first room had an air supply of $0.12m^3/s$, with an associated air change rate of 33.6/h. However, if the air change rate is calculated from the extract rate, which was $0.38m^3/s$, the air change rate was 106.3/h. The second room had an air supply of $0.122m^3/s$ and an extract rate of $0.273m^3/s$. This gave an air change rate, based on the air supply of 38.0/h and, when based on the extract rate, 85.0/h. In the first room, the measurement of the decay rate gave a local air change rate of 75.4/h and, if the average air change was based on the air supply rate, an ACE index of 2.2. However, if the average air change was based on the extract rate, the ACE index was 0.7. In the second room, the measurement of the decay of particles gave a local air change rate of 64.0/h. If the calculation of the ACE index was based on the air supply rate, it was 1.7, and if based on the extract rate it was 0.75. It would be expected that when testing a cleanroom that the ACE index would normally be calculated from the room's air supply rate and not the air extract rate. The reason for noticeable deviations of the ACE index from 1 could then be explained by extra clean air drawn into the room.

4 Discussion and Conclusions

This article investigates methods used to determine the ability of a cleanroom to recover from episodes of airborne contamination, and ensure that high concentrations of airborne contaminants are not found at important locations. The two cleanliness recovery methods given in ISO 14644-3 (2005) are considered, and how these tests might be improved to encompass these two objectives. The following improvements to ISO 14644-3 are suggested.

a) Both the '100:1 recovery time' and the 'recovery rate' tests measure the same fundamental property i.e. rate of decay of airborne contamination, and therefore only one test is needed. The 'recovery rate' method is the best choice, as a check can be carried out to ensure that the decay is exponential, and hence there has been sufficient mixing of supply and room air, re-establishment of the airflow pattern, no coincidence losses, and no influence from background contamination at the end of measurements. If the ISO 100:1 recovery time test is used, the test concentration should be measured at time intervals, and plotted, to ensure an accurate result.

b) The normal method of measuring the 'recovery rate' in cleanrooms is to take measurements in the middle of the cleanroom and assume the result is applicable to the whole room. This article shows that in a typical cleanroom, the result applies only to the measuring location. If information is required about the overall performance of the cleanroom then multiple locations should be sampled. The locations used to demonstrate compliance with ISO 14644-1 would be a suitable choice, although time constraints would allow only a proportion to be tested.

c) The ISO 14644-3 (2005) recovery test method fails to give a method for assessing whether the results obtained are satisfactory, or not. An assessment of the cleanroom's ability to recover from episodes of contamination and avoid high concentrations of contamination can be obtained by calculating an ACE index, which compares the air change rate at a test location to the average of the whole room. The method suggested uses the information generated during the ISO 14644-3 recovery rate test, and is therefore more convenient for use in cleanrooms. It gives the same result as the method given in ANSI/ASHRAE Standard 129, but is simpler both in concept and calculation. It also has much to commend its use in normal ventilated rooms.

Experiments were carried out in a variety of cleanrooms to determine their ACE indexes. The first set of experiments investigated a cleanroom where no diffusers were fitted to the air supply inlets, this air supply method being common in cleanrooms. The experiments showed that although the supply air flowed downwards and gave a high ACE index directly below the air inlet, and hence lower concentrations of airborne contamination, low ACE indexes were obtained elsewhere in the room. 4-way diffusers gave much better air mixing.

Investigations were carried out in eleven positive-pressure cleanrooms, which were shown to have ACE indexes with a mean of 0.93, and a range of between 0.67 and 1.28. ACE indexes greater than 1 are acceptable in cleanrooms as they show that the airborne contamination will be lower than average. However, if the ACE index drops below 1, airborne concentrations may be higher than desired, and it is suggested that if the value of the ACE index drops below 0.7 the reason for low results should be determined. If a retest confirms the result, then the airflow pattern in the room should be investigated using the airflow visualisation tests suggested in ISO 14644-3 to ensure no adverse air movements could lead to potential product contamination. Although ACE indexes greater than 1 need not be investigated, it should be understood that higher values are likely to be associated with low ACE indexes in other parts of the cleanroom. Investigations of ACE indexes that noticeably deviate from 1 can be aided by consideration of the following reasons that have been observed during these and previous investigations:

- Use of types of air supply diffusers that do not give good mixing of supply and room air;
- diffusers that normally give good air mixing but are operating at velocities that are lower or higher than their design values;
- the air supply is warmer or colder than the cleanroom, and results in streams of clean supply air that may not mix efficiently;
- obstructions, caused by large items of machinery and other equipment, making it difficult for supply air to penetrate areas of the cleanroom;
- short-circuiting of the air between the air supply inlet and air extracts;
- clean air devices, such as unidirectional workstations, which filter and supply clean air within the cleanroom, increasing the decay rate and the ACE index;
- air distribution systems, such as air supply inlets without a diffuser, or one-way diffusers, which direct a stream of clean supply air and give ACE indexes greater than 1 if measurements are made within the air stream, and less than 1 if out of the air stream.
- additional clean air entering the cleanroom from sources other than the room’s air supply inlets, as found in cascade and negative-pressure types of cleanrooms.

Cascade and negatively-pressurised cleanrooms were investigated and generally found to have high ACE indexes. The ACE indexes from five ‘cascade’ type cleanrooms were found to have a mean of 1.27, with a range of values from 0.90 to 1.82. ACE indexes measured in seven negatively-pressurised cleanrooms were higher (mean = 1.7, range = 1.2 to 2.1). The reason for high ACE index in these types of cleanrooms is almost certainly caused by additional clean air entering the room from adjacent cleaner areas. This is the normal situation in cascade-type cleanrooms, where air generally cascades from a cleaner area to a less-clean area. A similar situation may also occur in negative-pressure rooms, although areas outside the cleanroom are more likely to be of a lower quality, and low values of ACE indexes may be encountered.

It is clear from this study that good air mixing should not be assumed in cleanrooms, and poor air supply methods may lead to differences in the removal of airborne contamination and concentrations of airborne contamination. It is generally desirable that the airborne concentration should be even across cleanrooms to ensure that products are protected throughout the room. This requires ACE indexes close to 1 across the whole cleanroom. However, if this is not achieved, or considered not to be desirable, there should be no low ACE indexes at critical locations. To ensure this occurs, tests should be carried out by the ISO 14644-3 recovery rate test method that is extended to calculate ACE indexes.

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Annex: Comparison of Air Change Effectiveness (ACE) Index method given in ANSI/ASHRAE Standard 129-1997 (RA 2002) to that used in this article

A 1 Definition of Air-Change Effectiveness (ACE) index in ANSI/ASHRAE Standard 129

The ACE index is calculated in ANSI/ASHRAE Standard 129 by means of the following equation:

$$ACE = \frac{\tau_n}{A_i} \qquad \text{Eqn A1}$$

Where,

τ_n = nominal time constant

A_i = age of air at location, i

A 2 Age of air from tracer gas decay measurement

In a ventilated room, the age of the air at a point, i, is given in Appendix B of ANSI/ASHRAE Standard 129 by the following equation:

$$A_i = \frac{1}{C_0} \int_0^{\infty} C_i\ (t) dt \qquad \text{Eqn A2}$$

Where A $_I$ = age of air at location, i,
C_0 = initial concentration at time, t = 0,
and C_i (t) = concentration after time, t.

To integrate Equation 2, the equation has to be in a suitable form. The following Equation 3, which defines the exponential decay of airborne contamination in a room, can be used to achieve this:

$$C_i(t) = C_0 e^{-n_i t} \qquad \text{Eqn A3}$$

Where n_i = air change rate at location, i,
t = time between measurement of C_o and C

Substituting Equation A3 into Equation A2 gives the following:

$$\frac{1}{C_0} \int_0^{\infty} C_0 e^{-n_i t}\ dt \qquad \text{Eqn A4}$$

Simplifying Equation A4 produces the following definite integral:

$$\int_0^{\infty} e^{-n_i t}\ dt \qquad \text{Eqn A5}$$

The solution to the definite integral is:

$$\frac{1}{n_i} \qquad \text{Eqn A6}$$

Therefore:

$$\frac{1}{C_0} \int_0^{\infty} C\ dt = \frac{1}{n_i} \qquad \text{Eqn A7}$$

and therefore,

$$A_i = \frac{1}{n_i} \qquad \text{Eqn A8}$$

A3 Nominal time constant (τ_n)

The nominal time constant (τ_n) is defined in ANSI/ASHRAE Standard 129 as a reciprocal of the overall air change rate (N) in the room i.e.

$$\tau_n = 1/N \qquad \text{Eqn A9}$$

A4 Comparison of ACE index obtained by ANSI/ASHRAE standard 129 and the method in this paper

Equation A1 can now be written as follows:

$$ACE = \frac{\tau_n}{A_i} = \frac{\frac{1}{N}}{\frac{1}{n_i}} = \frac{n_i}{N} \qquad \text{Eqn A10}$$

However, $\frac{n_i}{N} = \frac{\text{local air change rate}}{\text{overall air change rate in room}} = \text{ACE index, as measured in this paper}$ Eqn A11

Therefore, the ACE index obtained by the method given in ANSI/ ASHRAE Standard 129 is the same as the ACE index obtained in this paper.