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Cleanrooms and associated controlled environments

Part 17: Particle deposition rate applications

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National foreword

This British Standard is the UK implementation of EN ISO 14644-17:2021. It is identical to ISO 14644-17:2021.

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European foreword

This document (EN ISO 14644-17:2021) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

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Endorsement notice

The text of ISO 14644-17:2021 has been approved by CEN as EN ISO 14644-17:2021 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 243, *Cleanroom technology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

A list of all parts in the ISO 14644 series can be found on the ISO website.

Introduction

Cleanrooms and associated controlled environments are used to control contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in industries such as aerospace, microelectronics, optics, nuclear, food, healthcare, pharmaceuticals, and medical devices.

ISO 14644-1:2015 considers airborne particles in cleanrooms and classifies cleanroom cleanliness by maximum permitted concentrations, and both ISO 14644-9:2012 and IEST-STD-CC1246E:2013 consider the concentration of surface particles. This document considers the rate of particle deposition onto cleanroom surfaces and is based on VCCN Guideline 9[5]. The particle deposition rate is important, as the probability of contamination by airborne particles onto contamination sensitive, vulnerable surfaces, such as manufactured products, is directly related to the particle deposition rate.

ISO 14644-3:2019 gives an overview of methods for the determination of deposition of particles, larger or equal to 0,1 µm. In this document, the focus is on the rate that macroparticles larger than 5 µm deposit on surfaces, and the application of this information to controlling contamination in cleanrooms.

Various sizes of particles are generated in cleanrooms by personnel, machinery, tools, and processes, and distributed by air moving about the cleanroom. According to ISO 14644-1, cleanrooms and controlled environments with a particle class of the ISO 5 series, or cleaner, contain zero or very low concentrations of airborne particles larger than 5 µm. However, in operating cleanrooms, many more particles in the size range of 5 µm to 500 µm, and greater, are found on surfaces than suggested by the classification limits of the size of particles given in ISO 14644-1. The main reason for this is that the largest particles in the range of sizes of macroparticles are not counted by particle counters because of deposition losses in sampling tubes, and at the entry to and within particle counters. Also, for the same reason, only a proportion of the smaller particles in the range of sizes is measured. In many cases, large particles cause contamination problems and their presence and potential for deposition onto contamination sensitive, vulnerable surfaces is best determined by measuring the particle deposition rate onto surfaces.

Particles smaller than 5 µm are most likely to be removed from the cleanroom air by the ventilation system but, for particles above 10 µm, more than 50 % is removed from the air by surface deposition. Above 40 µm, more than 90 % is deposited (see Reference [6]). The dominant deposition mechanism of this size of particles has been shown to be gravitational but air turbulence and electrostatic attraction can also cause deposition (see Reference [7]). These deposited particles can be re-dispersed by walking and cleaning actions, but not by air velocities associated with the cleanroom air. It is important that these particles are removed by cleaning.

The presence and redistribution of particles >5 µm in cleanrooms is mostly related to human or mechanical activity. In a cleanroom "at rest", there is likely to be little activity and dispersion of particles, and the concentration of particles larger than 5 µm is close to zero with no significant particle deposition. Therefore, it is only in the "operational" occupancy state that the particle deposition rate should be considered.

The particle deposition rate is an attribute of a cleanroom or clean zone that determines the likely rate of deposition of airborne particles onto cleanroom surfaces, such as product or process area. Using a risk assessment, the acceptable amount of contamination of a vulnerable surface can be defined, and the particle deposition rate can then be obtained that ensures that this amount of contamination is not exceeded.

Methods of measuring the particle deposition rate in a cleanroom or clean zone are given in this document. These are used during the operation of the cleanroom to ensure that the required particle deposition rate is obtained, and for monitoring the cleanroom and clean zones to demonstrate continuous control of airborne contamination. Monitoring the particle deposition rate also enables PDR peaks to be correlated with activities so as to detect sources of contamination, and indicate what changes are required to working procedures to reduce the contamination risk.

The particle deposition rate is the rate of deposition of particles onto surfaces over time, and can be calculated as the change of particle surface concentration per m^2 during the time of exposure in hours and can be expressed as Formula (1):

$$R_D = \frac{C_{f_D} - C_{i_D}}{t_f - t_i} \quad (1)$$

where

R_D is the deposition rate of particles equal to, or larger than D (μm) per m^2 per hour;

C_{f_D} is the final particle surface concentration (number per m^2) for particles equal to and larger than D (μm);

C_{i_D} is the initial particle surface concentration (number per m^2) for particles equal to and larger than D (μm);

t_f is the final time of exposure (h);

t_i is the initial time of exposure (h).

If the particle deposition rate is determined on, or in close proximity to, a vulnerable surface, such as product, then an estimate of the deposition of airborne particles onto the surface can be obtained by applying Formula (2):

$$N_D = R_D \cdot t \cdot a \quad (2)$$

where

N_D number of deposited particles larger than or equal to particle size D (μm);

t is the time the surface is exposed to particle deposition (h);

a is the surface area exposed to airborne contamination (m^2).

Some industries use cleanrooms to manufacture optical instruments and components, such as mirrors, lenses, and solar panels used in aerospace. The quality of these products is related to the amount of light absorbed or reflected by particles on the surface. Therefore, this document also considers particle obscuration rate of test surfaces exposed in cleanrooms in Annex C. Using the particle deposition rate of various particle sizes, the particle obscuration rate of airborne particles depositing onto a surface and obscuring light can be calculated and used in a similar way to the particle deposition rate to reduce the risk of surface contamination.

Cleanrooms and associated controlled environments —

Part 17: Particle deposition rate applications

1 Scope

This document gives direction on the interpretation and application of the results of the measurement of particle deposition rate on one or more vulnerable surfaces in a cleanroom as part of a contamination control programme. It provides some instructions on how to influence the particle deposition rate and reduce the risk of particle contamination on vulnerable surfaces.

This document gives information on how a cleanroom user can use the particle deposition rate measurements to determine limits that can be set for macroparticles on vulnerable surfaces. It also gives a risk assessment method by which an acceptable risk of deposition of particles onto vulnerable surfaces in a cleanroom can be established and, when this is not achieved, methods that can be used to reduce the particle deposition rate.

An alternative to the particle deposition rate is the particle obscuration rate which determines the rate of increase of coverage of particles onto an area of surface over time. The particle obscuration rate can be used in an analogous way to the particle deposition rate and the required particle obscuration rate for a specified surface can be calculated and the risk from deposited particles reduced.

This document does not:

— provide a method to classify a cleanroom with respect to particle deposition rate or particle obscuration rate;

— directly consider the deposition of microbe-carrying particles, although they can be treated as particles;

— give any consideration to surface deposition by contact as, for example, when personnel touch a product and contamination is transferred.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-3:2019, *Cleanrooms and associated controlled environments — Part 3: Test methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
cleanroom
room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.1]

3.2
clean zone
defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation, and retention of contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: A clean zone(s) can be a defined space within a *cleanroom* (3.1) or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

Note 4 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.2]

3.3
critical particle size
smallest *particle size* (3.7) that negatively impacts on product or process quality

3.4
critical location
location where a *vulnerable surface* (3.12) is exposed to particle contamination

3.5
operational
agreed condition where the *cleanroom* (3.1) or *clean zone* (3.2) is functioning in the specified manner, with equipment operating and with the specified number of personnel present

[SOURCE: ISO 14644-1:2015, 3.3.3]

3.6
particle
minute piece of matter with defined physical boundaries

[SOURCE: ISO 14644-1:2015, 3.2.1]

3.7
particle size
diameter of a sphere or the diameter of a sphere (circle) that encompasses a non-spherical particle, or an equivalent diameter

Note 1 to entry: The definition should be stated in relation to the measurement method.

Note 2 to entry: In ISO 14644-1, light scattering based detection is used. Other measurement methods yield different size definitions (see A.1).

3.8
particle deposition rate
PDR
number of particles depositing onto a known surface area during a known time of exposure

Note 1 to entry: It is expressed in number per m^2 per hour.

3.9
particle deposition rate level
PDRL
level of *particle deposition rates* (3.8) for a range of *particle sizes* (3.7)

3.10
particle obscuration rate
POR
rate of change of particle area coverage of a surface during time of exposure

3.11
test surface
surface of specific area and known surface cleanliness used to collect particles that deposit from the air in a specified time

Note 1 to entry: A test surface is used in this document to determine the *particle deposition rate* (3.8).

Note 2 to entry: A test surface can be a witness plate or an integral part of a measuring instrument.

3.12
vulnerable surface
surface whose functionality diminishes when particles larger than the critical size are present

3.13
witness plate
clean flat plate of a specified surface area used to collect particles that deposit from the air in a specified time

Note 1 to entry: A witness plate is exposed adjacent to a *vulnerable surface* (3.12) to obtain the particle deposition rate that occurs at that location.

Note 2 to entry: A witness plate is not normally part of a measuring instrument and, after exposure, the witness plate is taken to a measuring instrument for the counting and sizing of the particles deposited.

4 Symbols

a product area in m^2

A area of the silhouette of the observed particles (mm^2)

C_D particle concentration in number of particles $\geq D$ µm per m^2

D particle size in micrometres

F particle obscuration rate

L particle deposition rate level

N_D number of particles ≥D µm deposited onto a surface

η efficiency of detection method

O particle obscuration factor (in $mm^2 \cdot m^{-2}$)

R_D particle deposition rate in number of particles ≥D µm per $m^2 \cdot h$

t time of exposure

5 Particle deposition rate methodology

5.1 General

Particle deposition rate data obtained in a cleanroom can be used to establish the probability of airborne particles depositing onto a vulnerable surface during exposure and provide a methodology that supports the required quality of a cleanroom during operation. The information in 5.2 and 5.3 gives a method that can be used to establish the correct particle deposition rate cleanliness conditions in a cleanroom and associated controlled environments. This information is used to demonstrate continued control of these cleanliness conditions. ISO 14644-2 shall be considered as a guide for the development and application of a monitoring plan.

5.2 Establishing the particle deposition rate required for control of particle deposition on vulnerable surfaces

Establishing control of macroparticles in the controlled environment through use of the particle deposition rate is required when a new facility is designed, or when cleanliness requirements are changed in existing facilities. An assessment shall be made of the product attributes and the process activities performed in the cleanroom. Based on this assessment, the required degree of control of particle contamination shall be established using the following steps.

1) The surfaces in the cleanroom or associated controlled environments that are vulnerable to particle deposition shall be identified. This can be done by considering the manufacturing carried out in the cleanroom, the status of the technical installations, production equipment, and operational procedures.

2) The smallest particle size that impacts on product or production quality on each vulnerable surface (critical particle size) shall be determined.

   NOTE 1 Differences in particle type (metallic vs non-metallic, transparent vs opaque, microbial vs non-microbial) can lead to a particle-specific approach.

3) The maximum number of particles of the critical size that contaminates each vulnerable surface considered shall be determined.

4) Knowing the maximum number of particles of a critical size that is acceptable on each surface, the particle deposition rate or particle deposition rate level (see Table 1) at the critical particle size shall be determined.

5) The critical surface with the tightest requirements on particle deposition rate and particle deposition rate level will determine the particle deposition rate and particle deposition rate level for the critical area.

6) After the maximum particle deposition rate or particle deposition rate level requirements are defined for the critical area, the measurement method shall be chosen and put into operation. The

method can be selected based on sensitivity, required measurement frequency, and other factors such as ease of use. ISO 14644-3 can be consulted for information on measurement methods.

NOTE 2 Examples of the method described above are given in Annex E.

5.3 Particle deposition rate for demonstrating control of particle contamination

Demonstrating control of the particle deposition rate in a cleanroom over time is important to ensure that the quality of the facility remains constant. It is necessary to demonstrate control of the particle deposition rate by demonstrating that the required particle deposition rate limits are still achieved. Monitoring shall be carried out where the most vulnerable surfaces are located, or at a location that is in close proximity and representative of the location of the vulnerable surface.

The required frequency of monitoring shall be determined by the criticality of the product being manufactured and the measuring equipment available (see Clause 6).

Failure to achieve the required particle deposition rate limit may require an investigation to understand the cause of the failure. Depending on the failure cause, improvements to working, cleaning, and maintenance procedures may be required. If needed, changes in manufacturing equipment, or cleanroom design and ventilation can be implemented. Methods of reducing the risk of airborne contamination are discussed in Annex E.

6 Measurement of particle deposition rate

The method for measuring the particle deposition rate is based on the collection of particles onto a test surface of a known surface area over a known time period. The particle deposition rate is then calculated by using Formula (1).

The particle deposition rate shall be measured on, or in close proximity to, a vulnerable surface during the manufacturing carried out in the cleanroom. If required, the particle deposition rate can be measured at several locations. The result of the measurement can then be used to check whether the location complies with a specified maximum particle deposition rate, or maximum particle deposition rate level, for certain cumulative particle sizes.

The methods for collecting airborne particles onto a surface, sizing and counting these particles, shall be chosen with reference to ISO 14644-3. Additional information is available in ASTM E2088, ASTM 25 and ASTM F50. When choosing the counting and sizing apparatus, consideration shall be given to the detection of particles in the relevant size range. The area of the test surface also needs consideration, particularly if the particle deposition rate is to be measured within a restricted time.

The witness plate, or measuring instrument, shall be placed in the same plane, and as close as possible to the vulnerable surface. The test surface shall be at the same electrical potential. Particles collected on the test surface are counted and sized to obtain reproducible data and are used to obtain the particle deposition rate adjacent to the vulnerable surface being investigated.

NOTE Be aware that measurement equipment and witness plates can interfere with process activities. Therefore, the location for monitoring needs to be selected carefully.

Sampling shall only be carried out during manufacturing when the product or process is exposed to airborne contamination. The minimum expected count for the largest critical particle size under consideration shall not be less than 1, but desirably 5. If insufficient particles have been counted, the time for measuring the particle deposition rate during the manufacturing of products or process shall be extended to obtain a higher number of particles. It can be necessary to measure more than one manufacturing period. A method of calculating the sample time is given in A.3.3. If a suitable sample is not feasible, alternative measurement techniques shall be considered.

7 Particle deposition rate level

For a defined range of particle sizes, the particle deposition rate can be expressed as a particle deposition rate level, *L*. The particle deposition rate level expresses the particle deposition rate over a range of particle sizes, in a similar way to that used in ISO 14644-9 to expresses surface particle concentration. This allows the concentration of particles at one size to be converted to a concentration at another size, and it can be used, for example, when the particle deposition rate is measured at one particle size but the critical particle size is different.

The particle deposition rate level is obtained using typical size distributions found in cleanroom that show the particle deposition rate is in direct proportion to the cumulative particle size. A typical size distribution is shown later in Figure B.3. The particle deposition rate levels are calculated by means of Formula 3 by assuming a linear distribution and a reference particle size of 10µm.

$$L = \frac{R_D \cdot D}{10} \quad (3)$$

Table 1 gives examples of *L* over a range of different cleanliness levels in orders of magnitude.

Table 1 — Particle deposition rate levels in orders of magnitude

Particle deposition rate level	Number of particles per m² per hour						
	≥5 µm	≥10 µm	≥20 µm	≥50 µm	≥100 µm	≥200 µm	≥500 µm
1	2,0	**1,0**	0,5	0,2	0,1	0,05	0,02
10	20	**10**	5	2	1	0,5	0,2
100	200	**100**	50	20	10	5	2
1 000	2 000	**1 000**	500	200	100	50	20
10 000	20 000	**10 000**	5 000	2 000	1 000	500	200
100 000	200 000	**100 000**	50 000	20 000	10 000	5 000	2 000
1 000 000	2 000 000	**1 000 000**	500 000	200 000	100 000	50 000	20 000

If the particle deposition rate for different size of particles at intermediate levels of *L* is required, Formula (4) can be used:

$$R_D = \frac{10L}{D} \quad (4)$$

If the particle deposition rate is required for another particle size at the same PDRL, Formula (5) can be used:

$$R_{D_N} = R_{D_O} \cdot \frac{D_O}{D_N} \quad (5)$$

where

R_{D_O} is the original particle deposition rate at particle size D_O;

R_{D_N} is the new particle deposition rate at particle size D_N;

D_O is the original cumulative particle size (µm);

D_N is the new cumulative particle size (µm).

The particle deposition rate level depends on the rate of airborne dispersion of particles from sources of contamination, and the particle removal efficiency of the ventilation system. The PDRL can be reduced by removing or reducing particle sources and/or by improving the removal efficiency of the ventilation system. However, the removal efficiency reduces for increasing particle size (see Reference [6]).

To establish and maintain control of the particle contamination by surface deposition required for vulnerable surfaces, it is necessary to set particle deposition rate limits that shall not be exceeded. The particle deposition rate limit depends on the acceptable surface contamination, which can be determined by a risk assessment, the vulnerable surface area, the critical particle size and the expected time of exposure (see A.3.3 for an example).

8 Documentation

By agreement between customer and supplier, the following information and data shall be recorded:

a) name and address of the testing organization, and the date on which the measurement was performed;

b) type of measurements and measuring conditions;

c) a reference to this document (i.e. ISO 14644-17);

d) clear identification of the physical location of the cleanroom or clean zone tested (including reference to adjacent areas if necessary), and coordinates of all sampling locations;

e) specified designation criteria of the cleanroom or clean zone, including the ISO 14644-1 classification, and the relevant activities in the occupied state;

f) details of the measurement instrument used to determine the particle deposition rate, including the identification of the measurement instrument, information on its current calibration certificate, and any special conditions relating to the measurement method;

g) details of the type of test surface used with witness plate or measuring instrument;

h) initial counts of surface cleanliness on test surface(s) in the case of witness plates method;

i) details of time of exposure;

j) a log of scheduled and unscheduled activities and incidents during exposure;

k) cumulative particle size(s) that are measured;

l) test results with background counts, or previous counts, subtracted;

m) statement regarding compliance with the claimed particle deposition rate level designation;

n) any other specific requirements that are relevant to the particle deposition rate and particle deposition rate level.

Annex A
(informative)

Measurement of particle deposition rate

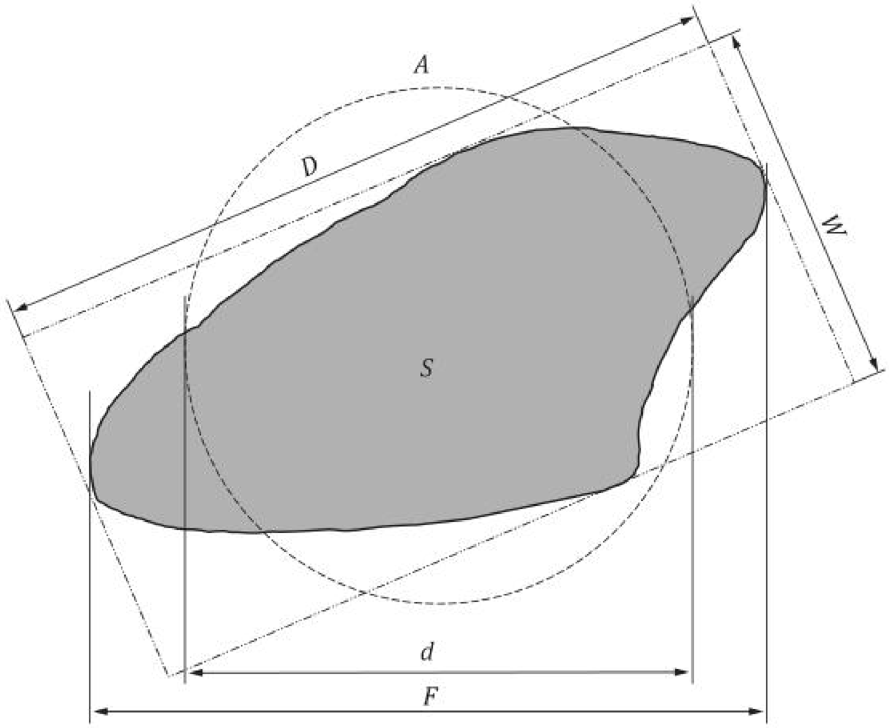
A.1 General

The basic principle of particle deposition rate measurement is the collection of particles on a witness plate or a test surface of an instrument, where the particles are counted and measured.

A witness plate method is usually accompanied by an off-line particle analysis technique. Measurement instruments containing a cleanable or replaceable test surface have a test surface and measurement technique integrated into one sensor unit. This enables it to measure the surface cleanliness on-line at frequent intervals.

A.2 Particle size

A particle is a 3-dimensional object, and its exact size can be determined by its diameter only if it is spherical. The size of particles measured on a witness plate or by an instrument varies according to the method used. The particle size is normally measured by microscopy or by an equivalent optical measurement system. In both systems, a 2-dimensional silhouette (projected surface area) of the particle is observed.



Key

S silhouette of particle
d equivalent diameter
F Feret diameter
D length of the particle
A equal area circle
W width

Figure A.1 — Dimensions used to measure particle size

Alternative methods of sizing are shown in Figure A.1 and described as follows.

— Equivalent diameter, *D*: This is normally based on the physical properties measured, such as light scattering, where the amount of light scattered by a particle is related to the size of the particle. Alternatively, the equivalent diameter can be calculated from the measured surface area, *A*, by Formula (A.1):

$$D=2\sqrt{\frac{2A}{4\pi}} \quad \text{(A.1)}$$

where

D is the equivalent particle diameter (µm);

A is the area of the silhouette of the observed particle (µm^2).

If the particles are sized microscopically by a person, the particle size can be obtained by comparing it to a series of circles on a calibrated eyepiece. Another approach is to measure the smallest inner and largest outer circles that contain the particle dimensions, and use the average as the equivalent diameter.

— Largest dimension.

— Feret diameter (calliper diameter), which is the largest dimension in a horizontal or vertical direction.

The selection of the particle size that is measured is mainly determined by the type of instrument used. In monitoring, it is important to use the same method for all measurements.

The particle area can be calculated from the equivalent diameter, or the length and width of the particle, or by measurement of the number of (sub)pixels of a detector that can fit into the silhouette of the particle.

A.3 Particle deposition rate measurements

A.3.1 Measuring efficiency

If the detection efficiency of the applied measurement method is not 100 % as indicated in Formula 2, the formula can be modified to account for the efficiency of the detection method by the insertion of η, as shown in Formula (A.2), correcting for the failure to count particles, or to count particles that are not there.

$$N_D = \eta \cdot R_D \cdot t \cdot a \qquad \text{(A.2)}$$

If a witness plate is used with a microscope, it is likely that the detection efficiency is close to 100 %. Similarly, instruments have a high efficiency and Formula (A.2) can normally be used without the addition of η. However, if the measuring efficiency is known, this can be added to Formula (A.2) to increase its accuracy.

Another point to be considered is the accuracy of the sizing, which in the case of an instrument is affected by the pixel size of the digital imaging system used to determine the particle size. However, this is only the case for the smallest sizes of particles that are measured and this impact is reduced by the cumulative size approach.

A.3.2 Particle deposition measurement instruments and witness plates

Particle deposition rate can be determined by measuring and counting particles deposited on a witness plate or test surface during exposure for a known time. A witness plate can be analysed under a microscope by a person, or with a microscope equipped for particle analysis by scanning and image processing. Particle deposition rate measurement is the measurement of macroparticles (particles ≥5 µm) and is normally presented as cumulative sizes.

Particle deposition measurement instruments can measure macroparticles with a lower size of particles that are equal to, and greater than, 5 µm, 10 µm, 15 µm or 20 µm. Measurement instruments should be considered with respect to their minimal particle size, measurement interval and measurable area of the test surface. A description of typical examples of these instruments is given in References [11], [12] and [13].

Particle obscuration (rate) of particles (see Annex C) can be determined by measuring the area covered by particles deposited on a witness plate or test surface of a measuring instrument during exposure for a known time. Particle obscuration is expressed as the ratio of the total particle surface area to the measured sample area in parts per million (ppm), or percentage area coverage. Alternative measurement units are $\mu m^2 \cdot mm^{-2}$, with μm^2 for the total particle surface area, and mm^2 for the area sampled.

A.3.3 Required measurement time of particle deposition rate

A sufficiently large sample should be taken to ensure the count of the required size of particle is accurate. To ensure this, a count of at least 1, but desirably 5, should be obtained. The example below shows how this can be done.

EXAMPLE A product is exposed during assembly to airborne contamination for 12 min per product. The particle deposition rate is measured by an instrument with a test area of 25 cm^2 at a particle size ≥20 µm.

The particle deposition rate level required to control airborne contamination is 2 000 particles ≥10 µm per m^2 per hour, which, as calculated by Formula (5), is equivalent to an intermediate particle deposition rate of 1 000 particles ≥20 µm per m^2 per hour.

Knowing the maximum particle deposition rate is 1 000 particles depositing on 1 m^2 (10 000 cm^2) per hour, then the time for a maximum count of 1 on a test surface of 25 cm^2 can be calculated as follows:

Question: If it takes 1 h for 1 000 particles to deposit on 10 000 cm^2, then how long does it take 1 particle to deposit on 25 cm^2?

Answer:

$$t = 1 \times \frac{1}{1\,000} \times \frac{10\,000}{25} = 0{,}4 \text{ h or } 24 \text{ min}$$

If the minimum count on the test surface needs to be 5, then, $t = 1 \times \frac{5}{1\,000} \times \frac{10\,000}{25} = 2 \text{ h}$.

So, when the time of exposure of the product to contaminated air is 12 min, the assembly of at least 2 products, and preferably 10 products, should be measured.

Annex B
(informative)

Examples of particle deposition rate measurements

B.1 Example of particle deposition rate measurements at a critical location

A glass witness plate with a collection surface area of 64 cm^2 was selected as a test surface and exposed for 4 h at a cleanroom location that is adjacent to a vulnerable surface (critical location). For diagnostic reasons, the following particle sizes were measured: ≥10 µm, ≥20 µm, ≥50 µm, ≥100 µm, ≥200 µm and ≥500 µm.

The initial surface cleanliness of the witness plate was measured prior to exposure, i.e. background count, and is given in Table B.1. Table B.1 also gives the particle counts measured on the witness plate after exposure for 4 h. By deducting the background count from the count after 4 h, the number of airborne particles that deposit on the witness plate over 4 h is obtained.

Table B.1 — Determination of particle deposition rate and particle deposition rate level

Particle size	≥10 µm	≥20 µm	≥50 µm	≥100 µm	≥200 µm	≥500 µm
Initial count on 64 cm^2 witness plate	3	1	0	0	0	0
Count on witness plate after 4 h of exposure	16	13	5	2	1	0
Number deposited on 64 cm^2 in 4 h	13	12	5	2	1	0
R (particles ≥D µm per m^2 per hour)	508	469	195	78	39	0
Particle deposition rate level from Table 1	1 000	1 000	1 000	1 000	1 000	0
$L = R_D D/10$ (calculated)	508	938	977	781	781	0

The particle deposition rate (number per m^2 per hour) for each considered cumulative particle size is then calculated by Formula (1). The particle deposition rate level is then determined by comparing the particle deposition rate values of each particle size with the particle deposition rate levels given in Table 1. The highest value is the particle deposition rate level value. In this example, a L of 1 000 is obtained for the cumulative particle sizes of ≥10 µm, ≥20 µm, ≥50 µm, ≥100 µm and ≥200 µm.

Alternatively, the particle deposition rate level can be calculated for each particle size by Formula (3), which is R_D $D/10$. The highest value (977) can then be compared to the L values in Table 1, to obtain a L of 1 000.

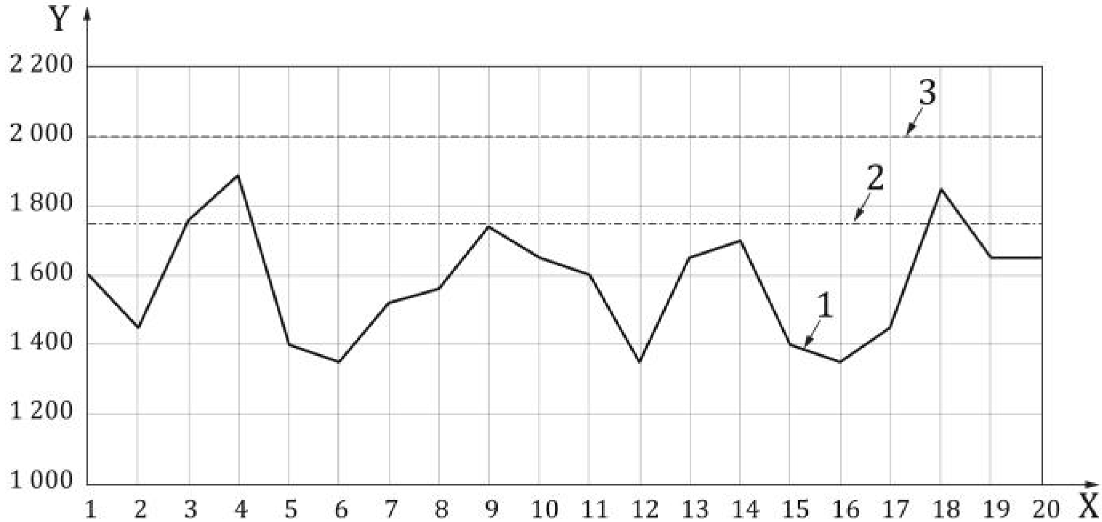
B.2 Examples of monitoring the particle deposition rate at a critical location

From the risk assessment, a critical location in a cleanroom can be specified as well as the target particle deposition rate, or alert and action levels of the required particle deposition rate or particle deposition rate level. If the R_D exceeds the target or action values, then appropriate control measures can be taken to reduce the R_D.

As an example, during every working day, the particle deposition rate during 4 h is measured on a 50 cm^2 witness plate. For each measurement, the number of particles ≥10 µm per m^2 per hour is calculated.

Figure B.1 shows an example of the average weekly particle deposition rate for particles ≥10 µm over a period of 20 weeks. The particle deposition rate is taken from the daily measurement over 4 h at a vulnerable location in a cleanroom. In this example, an alert level is set at 1 750 ≥10 µm per m^2 per hour to prevent exceeding the required PDRL of 2 000 ≥10 µm per m² per hour. In this example, this is also the action limit.

The action limit was not exceeded during monitoring and no risk reduction measures of the type given in Annex E needed to be applied. The alert level is set at 1 750 ≥10 µm per m² per hour to give an alert when the PDRL is approaching the action value. This alert level was exceeded twice, and on each occasion an increased surveillance of the particle deposition rate results was initiated.



Key

X working days

Y PDRL

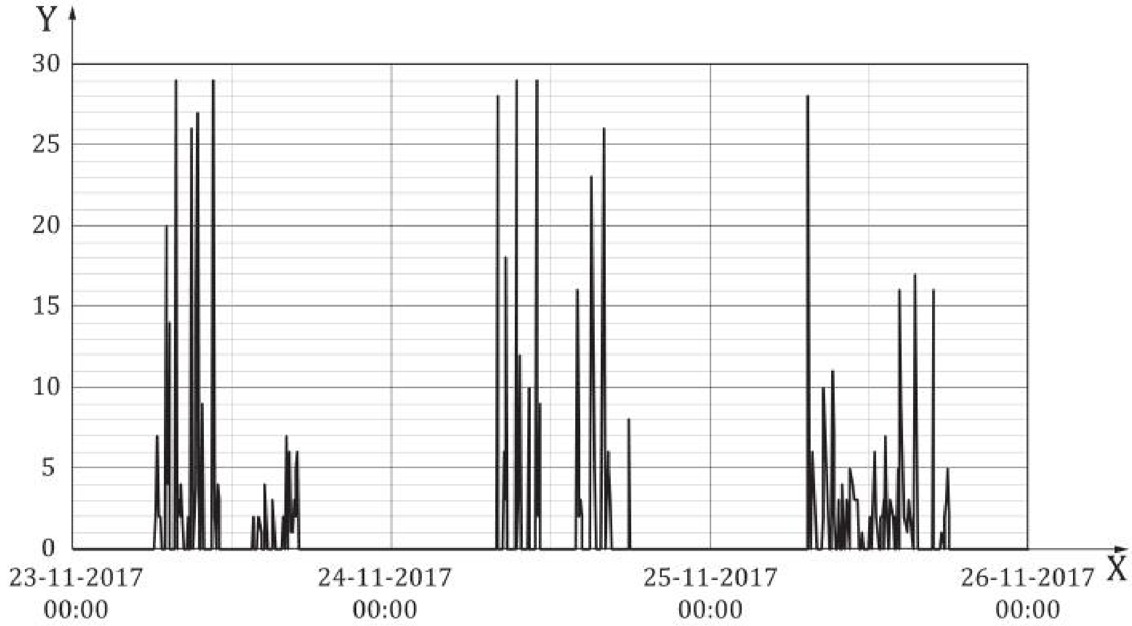
1 particle deposition rate level each day in number of particles ≥10 µm per m² per hour

2 alert limit for particle deposition rate level

3 PDRL limit, action limit for particle deposition rate level

Figure B.1 — Example of daily monitoring of particle deposition rate level by a witness plate method

Measurement instruments that can measure particle deposition rate at short intervals are available (real time monitoring). As an example, a sensor with a test surface of 50 cm² and a sampling time of 5 min is used. Figure B.2 shows an example of an operational sampling period of 72 h. It can be seen that the cleanroom is only used during daytime. This means that the actual operational time of the instrument is about 36 h. If required, the time that deposition events occur can be correlated with activities that occur in the cleanroom to identify potential sources of contamination.



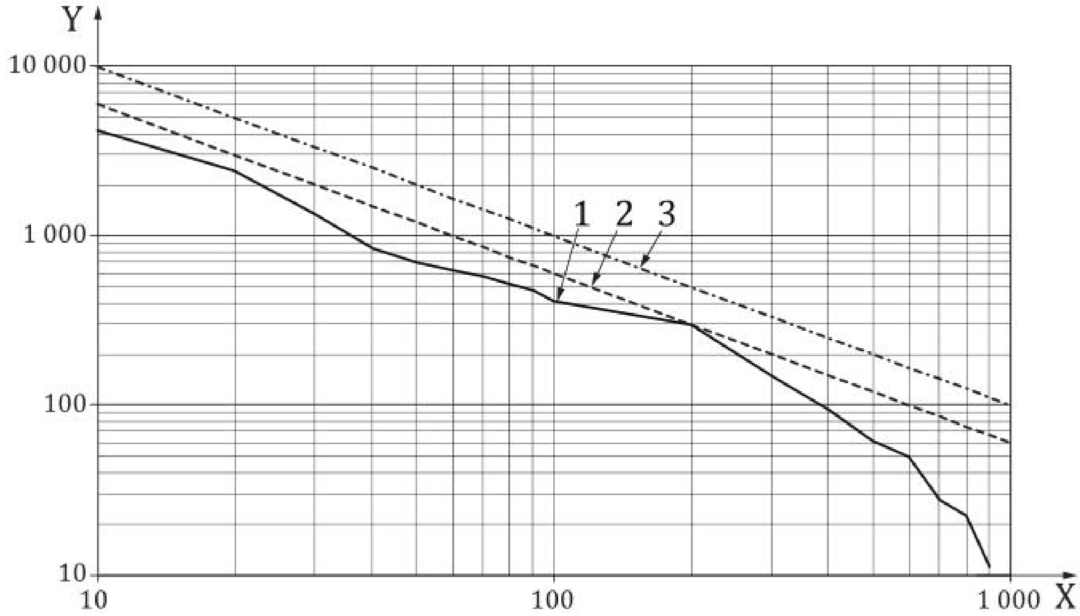
Key

X time

Y *R*(10) = deposition rate of particles ≥10 µm per m^2 per sample time of 5 min

Figure B.2 — Example of a real-time measurement of deposition of particles

If required, the results obtained from a witness plate, or real time sensor, can be used to obtain a particle size distribution. Figure B.3 shows such a distribution obtained from the previous example when using the real time sensor over a 36-hour sampling time. Figure B.3 also shows the *L* of 10 000.



Key

X cumulative particle size in μm

Y particle deposition rate in cumulative number of particles per $m^2 \cdot h$

1 R_D

2 measured particle deposition rate level

3 closest limit for particle deposition rate level

Figure B.3 — Example of the particle size distribution of the particle deposition rate and particle deposition rate level

Annex C
(informative)

Measurement of the particle obscuration

C.1 General

In some cleanroom manufacturing industries, such as optical components or instruments, and aerospace, the quality of products such as mirrors, lenses and solar panels is related to the amount of light absorbed or reflected by particles on surfaces. In these situations, rather than measuring the particle deposition rate, it is more relevant to measure the proportion of surface that is obscured by particles. IEST-STD-CC1246E:2013 gives a method for calculating the amount of obscuration of a surface by measuring the longest length of a particle and using empirical conversion factors to calculate the surface area of the particles. The method in this annex uses a different approach that makes it more applicable to equivalent particle sizes and, therefore, measuring instruments. The method is based on a method described in ECSS-Q-ST-70-50C:2011.

The method described in this annex firstly measures the particle obscuration factor and then calculates the particle obscuration rate[15].

The particle obscuration factor is calculated with Formula (C.1):

$$O = \frac{A}{a} \quad (C.1)$$

where

O is the particle obscuration factor in $mm^2 \cdot m^{-2}$;

A is the particle area coverage, the total surface area of particles in mm^2;

a is the area of surface sampled in m^2.

By measuring the particle obscuration factor over time, the particle obscuration rate can be obtained, which is an index analogous to the particle deposition rate[15] [see Formula (C.2)].

$$F = \frac{O}{t} \quad (C.2)$$

where

F is particle obscuration rate (particle area in mm^2 per m^2 per hour);

O is the particle obscuration factor in $mm^2 \cdot m^{-2}$;

t is the time the surface is exposed to particle deposition (h).

Instruments that can directly measure obscuration are available.

If the customer and the supplier agree on a maximum amount of particle obscuration on a surface in terms of the particle obscuration factor, the particle obscuration rate can be used to set up the proper control of contamination that meets the agreed particle obscuration factor.

The particle obscuration rate can also be used to determine the acceptable particle area coverage on a critical surface of a known surface area after exposure for a given time [see Formula (C.3)]:

$$A = F \cdot t \cdot a \quad (C.3)$$

where

- F is particle obscuration rate (particle area in mm^2 per m^2 per hour);
- t is the time the surface is exposed to particle deposition (h);
- a is the surface area exposed to airborne contamination (m^2).

C.2 Measurement of particle obscuration

The particle obscuration factor can be measured by exposing a test surface to airborne deposition, and obtaining the number and surface area of particles that deposit from the air onto the test surface. If the change in particle obscuration factor over time is measured, the particle obscuration rate is obtained.

The size and number of particles deposited onto a known surface area can be obtained by microscopic measurement, or by instruments. To calculate the surface areas of the particles, the cumulative counts are not measured but particles within size ranges.

The particle dimensions that are measured by different measuring methods are explained in Annex A and this particle obscuration factor method uses the equivalent diameter, which takes account of the uneven shape of the particle by obtaining the diameter of a sphere that has the same projected area as the particle. The total particle area, which is the surface area of all particles on the test surface, is calculated by Formula (C.4). After this is calculated, the particle obscuration factor is obtained by use of Formula (C.1).

$$A = M + \sum_{i=1}^{n} N_i \cdot \frac{\pi}{8}\left(d_i^2 + D_i^2\right) \quad \text{(C.4)}$$

where

- A is total particle area;
- M is total area of particles ≥100 µm;
- i is the range number;
- d_i is the lower limit of the i^{th} size range;
- D_i is the upper limit of the i^{th} size range;
- N_i is the number of particles counted in the i^{th} size range of differential particle size distribution.

It should be noted that in Formula (C.4), the particle area of each size is obtained from the average of the lower and upper sizes of particles.

Any particles ≥100 µm should be individually sized and their surface area calculated from formula (C.5).

$$A_i = \frac{\pi}{4} D_i^2 \quad \text{(C.5)}$$

where

- A_i is the surface area of an individual particle;
- D_i is the equivalent diameter of that particle.

Table C.1 shows the results of an example used to illustrate the calculation of the particle obscuration factor.

Table C.1 — Calculation of particle obscuration factor and particle obscuration rate

Particle size (minimum)	**Particle size** (maximum)	**Particle count**	**Particle area** (μm^2) $= N \cdot \pi / 8(d^2 + D^2)$
5	15	4 000	392 699

Particle size (minimum)	**Particle size** (maximum)	**Particle count**	**Particle area** (μm²) = $N \cdot \pi/8(d^2 + D^2)$
15	25	500	166 897
25	50	150	184 078
50	100	50	245 437
100	—	2	15 710
250	—	1	49 094
520	—	1	212 399
750	—	1	441 964
1 100	—	1	950 455
Total particle area (μm²) =			2 658 612
Total particle area (mm²) =			2,66
Sampled area = 0,000 4 m²		F = 6 650 mm²·m⁻² O = 665 mm²·m⁻²·h⁻¹	

The upper and lower particle size limits for each range are given, along with their counts on the test surface. The surface areas of all the particles in each size range below 100 μm are calculated with Formula (C.4) and given in the last column. Particles of 100 μm and greater, are individually sized and their surface area calculated.

By summing the surface areas of all particles given in the last column of Table C.1, the total surface area is found to be 2,66 mm^2. Knowing the test area is 4 cm^2 (0,000 4 m^2), the particle obscuration factor is calculated with Formula (C.1) to be 6 650 per $mm^2 \cdot m^{-2}$. As the test surface was exposed for 10 h, the particle obscuration rate is 665 per $mm^2 \cdot m^{-2} \cdot h^{-1}$.

Annex D
(informative)

Relationship between particle deposition rate and airborne concentration of particles

Table 1 can be used to set the particle deposition rate level for particles depositing from air onto a vulnerable surface. When these limits are set, there can be a need to provide a new or upgraded cleanroom or clean zone with a ventilation system that ensures that the particle deposition rate level is unlikely to be exceeded. However, ventilation systems cannot be designed from knowledge of the particle deposition rate level but require information on airborne concentrations of particles (ISO 14644-1 class) to calculate the air supply rate volumes (see Reference [16]).

The relationship between the particle deposition rate and concentration of particles ≥5 μm/m³ has been investigated in a wide variety of cleanroom classes (see Reference [17]). Further research has confirmed the correctness of this information (see Reference [18]). Using this relationship, the ISO 14644-1 class that approximately correspond to a range of particle deposition rate levels can be obtained. These are given in Table D.1.

Table D.1 — Relationship of particle deposition rate levels to airborne concentration of particles ≥5 μm and ISO 14644-1 class limits

Particle deposition rate level	**1**	**10**	**100**	**1000**	**10 000**	**100 000**	**1 000 000**
Maximum particle deposition rate of particles ≥5μm (number per m² per hour)	2	20	200	2000	20 000	200 000	2 000 000
ISO 14644-1 class – in operation	1,5	3,0	4,0	5,5	7,0	8,0	9,0

The relationship given in Table D.1 between PDRL and ISO 14644-1 class limits should not be considered to be accurate, as it is likely to vary according to the airborne conditions and size distribution of airborne particles in a cleanroom or clean zone. In addition, the concentration of particles below 200 particles ≥5 μm per m² per hour is an extrapolation from the information given in ISO 14644-1 (see Reference [19]).

Table D.1 should therefore only be used in designing cleanrooms where actual data is unavailable.

Annex E
(informative)

Assessment and control of particle deposition

E.1 General

A methodology is given in 5.2 for establishing control of airborne contamination in a cleanroom by use of the particle deposition rate. This methodology is based on a risk assessment (see Reference [20]) where risk of particle contamination in a cleanroom can be assessed by a combination of the severity of the risk and its occurrence (see References [21] and [22]).

In a cleanroom where the impact from airborne deposition onto a critical surface, such as a product or process, is being assessed, the risk can be calculated by Formula (E.1):

$$N_\mathrm{D} = R_\mathrm{D} \cdot a \cdot t \tag{E.1}$$

NOTE In failure mode and effect analysis (FMEA), severity is related to customer dissatisfaction or damage to equipment of people and scored in a different way.

Formula (E.1) can be reformed to calculate the particle deposition rate required for an acceptable amount of contamination from particle deposition.

$$R_\mathrm{D} = \frac{N_\mathrm{D}}{a \cdot t} \tag{E.2}$$

To calculate the risk to product from the deposition of particles, Formula E.1 can be used, and Formula E.2 can be used to provide the airborne conditions of particle deposition rate required to reduce risk to an acceptable level.

To obtain the information required to calculate risk, the first three steps given in 5.3 should be used. These are as follows:

1) the surfaces in the cleanroom or associated controlled environments that are vulnerable to particle deposition shall be identified;

2) the smallest particle size that impacts product or process quality on each vulnerable surface (critical particle size) shall be determined;

3) the maximum number of particles of the critical size that causes contamination at each vulnerable surface considered shall be determined.

These three steps require knowledge of the vulnerable surface and insight into the causes of the failure by particle contamination. This information can be obtained by performing:

— an analysis on the impact of contamination of the surface in the (future) function of a product or process where the vulnerable surface will be used;

— tests or simulations with various cleanliness classes of the considered vulnerable surface; and/or

— an analysis of the contamination that caused failure or quality loss.

The number of particles that deposit onto a vulnerable surface of a known surface area that is exposed for a known time can be calculated by Formula (E.1) and this is demonstrated by an example given in E.2.

The risk to a vulnerable surface can be related to the properties of particles other than size. If particles possessing an undesirable property are identified and their particle deposition rate determined, then these particles can be treated in the same way as cumulative particle sizes using the method described in this annex.

Determination of the maximum number and size of particles is highly surface specific and should be carried out for each individual type of surface. For process change it is recommended to re-evaluate the risks.

The second part of the methodology described in 5.2 is for calculating the particle deposition rate (or particle deposition rate level) in a cleanroom for an acceptable amount of particle deposition onto vulnerable surfaces. Formula (E.2) can be used and an example of the application of this method is given in E.3. When the particle deposition rate is found to be too high, the methods explained in E.4 can be used to reduce the risk from one or more of the risk factors that contribute to particle deposition.

E.2 Example of a calculation of the risk from particle deposition onto a vulnerable surface

The amount of deposition of airborne particles onto a vulnerable surface can be calculated from the particle deposition rate (see References [22] and [23]) and this method is illustrated by an example.

A product manufactured in a cleanroom has a vulnerable surface area of 10 cm^2 (10^{-3} m^2) and exposed to airborne contamination in a cleanroom for 5 hours during production. Taking into consideration the properties that act with size to affect reliability, the product's reliability was considered to be affected by particles ≥20 µm. The $R_{(20)}$ was measured adjacent to the product by an instrument or witness plate with a measuring efficiency close to 100 %. It was found to be 1 000/m^2/h. Therefore, the number of particles ≥20 µm that deposit onto the surface of the product can be calculated by Formula (E.1) as follows:

$$N_{(20)} = R_{(20)} \cdot a \cdot t = 1\,000 \times 10^{-3} \times 5 = 5 \quad \text{(E.3)}$$

A fraction of this number of particles was considered to cause a defect in the product and the risk from particle deposition in this example is considered to be too high. Clause E.4 considers how the risk can be reduced.

E.3 Example of calculation of the particle deposition rate required for an acceptable amount of particle contamination of surfaces

If the number of particles of a given cumulative size is known to cause unacceptable problems when they deposit onto a product or process, the required particle deposition rate or particle deposition rate level of a cleanroom or clean zone can be calculated.

EXAMPLE Using the example discussed in E.2, and consideration of the number and size of particles that affect the reliability of the product, as well as the economics of the process (cost of yield loss with respect to additional prevention costs), it was concluded that particle deposition onto the product should not be more than 1 particle ≥20 µm. The product has a vulnerable horizontal surface area of 10 cm^2 (10^{-3} m^2), and is exposed in cleanroom air for 5 h. The particle deposition rate for particles ≥20 µm that is not to be exceeded can now be calculated with Formula (E.2) and found to be 200/m^2·h:

$$R_{(\geq 20\,\mu\text{m})} = \frac{N_D}{a \cdot t} = \frac{1}{0{,}001 \times 5} = 200\ /\text{m}^2\cdot\text{h}$$

By reference to Table 1, it is found that a R(≥20 µm) of 200/m^2·h is equivalent to a particle deposition rate level of 1 000.

Alternatively, the PDRL can be calculated with Formula (3) as follows:

$$\frac{200 \times 20}{10} = 400$$

If the $R(\geq 20\ \mu m)$ measured in the cleanroom is not equal to or less than 200 per $m^2 \cdot h$, improvements to disciplines and control methods are required (see E.4.1). If a new cleanroom is being designed, or upgrade, then the ventilation system should be designed to provide a $R(\geq 20\ \mu m)$ of $200/m^2 \cdot h$ (see E.4.2).

The above calculation assumes that when the critical surface is exposed to airborne contamination, it is free of surface contamination. However, surface particles can have been ineffectively removed during cleaning, or not cleaned. If this is so, then the above calculation can be modified as follows.

If the total number of the critical size of particle on the critical surface, before being exposed to airborne contamination, is 0,2 per product, then the particles that come from airborne deposition is 1 − 0,2 = 0,8. The particle deposition rate is then calculated by the same method as described above by use of Formula (E.2).

$$R_{(\geq 20\ \mu m)} = \frac{N_D}{a \cdot t} = \frac{0,8}{0,001 \times 5} = 160\ /m^2 \cdot h$$

By reference to Table 1, it is found that a $R(\geq 20\ \mu m)$ of $160/m^2 \cdot h$ is equivalent to a particle deposition rate level of 1 000.

Alternatively, an intermediate PDRL can be calculated by use of Formula (3) as follows:

$$\frac{160 \times 20}{10} = 320$$

E.4 Reduction of the risk of surface contamination from depositing particles

E.4.1 Reduction of risk of surface contamination by improving cleanroom procedures

If the particle deposition rate is measured in an operational cleanroom, and found to be unsatisfactory, the particle deposition rate can be reduced by lowering the values of one, or more, of the three risk factors shown in Formula (E.1), namely, time of exposure, exposed surface area, and particle deposition rate. The first two risk factors usually require a change in the manufacturing method to reduce these risk factors but such production modifications are application-dependent and outside the scope of this document. This annex focusses on reduction of the risk to products by reducing the particle deposition rate during manufacturing.

The monitoring of the particle deposition rate over time at a location adjacent to the vulnerable surface obtains particle deposition rate results of the type shown in Figure B.2. Sources of contamination can be ascertained by observing what procedures are associated with peaks of particle deposition rate. Possible sources of airborne contamination, and methods used to reduce airborne dispersion, include the following:

1) personnel, with less people and lower activity that is associated with a lower dispersion of airborne particles;

2) personnel garments, with improvements to design and fabric that are associated with minimising dispersion of airborne contamination;

3) changing procedure and design of the changing facility to limit or control the cross contamination from surfaces in the changing room, and from other people going in or out the cleanroom;

4) cleaning frequency of garments;

5) working methods and behaviour of personnel to reduce activity and particle dispersion;

6) entrance and exit procedures;

7) surface cleaning programme and cleaning methods for floors, work surfaces, tools and equipment;

8) cleaning of incoming goods;

9) routing of people and goods (logistics).

These, and any other potential sources of airborne contamination, should be investigated to obtain evidence as to the main sources of contamination. Disciplines and control methods should then be introduced, or improved, to reduce the dispersion of particles into cleanroom air, and the impact on the particle deposition rate ascertained. Further information on cleanroom disciplines and control methods used to reduce airborne contamination is available (see References [21],[23] and[24]).

In the example discussed in E.2, the $R_{(\geq 20\ \mu m)}$ was measured during manufacture and found to be 1 000/m^2·h. This was considered too high, as the calculation in E.2 showed that a particle deposition rate of around 200/m^2·h was the desirable particle deposition rate. Improvements were made to the effectiveness and frequency of cleaning of cleanroom surfaces, and the cleanroom clothing was upgraded from smocks to full-body coveralls made from fabrics that effectively filter body emissions. These changes were found to reduce the $R_{(\geq 20\ \mu m)}$ from 1 000/m^2·h to 100/m^2·h. Using Formula (E.1), it can be calculated that the risk from particle deposition is reduced from about 5 to 0,5 particles per product, and this improvement was considered acceptable.

E.4.2 Example of designing and upgrading the ventilation to achieve the correct particle deposition rate level

If the particle deposition rate cannot be reduced sufficiently by improved operational procedures, it can be necessary to improve the ventilation system by designing a new cleanroom, or upgrading an existing one. This clause gives information on how the ventilation system can be designed for a given particle deposition rate or particle deposition rate level. This method is more successful in reducing smaller sizes of macroparticles that are removed by the air exhaust before they deposit on surfaces, rather than larger particles which deposit more quickly on surfaces and need to be removed by cleaning.

The normal method of designing a ventilation system to achieve a required cleanliness of cleanroom needs information on the airborne particle concentrations, i.e. the class limits given in ISO 14644-1. Annex D gives information on the relationship of particle deposition rate level to the ISO 14644-1 classification. This relationship can be used as the basis of a design.

The example discussed in E.4.1 found that a $R_{(\geq 20\ \mu m)}$ of 200/m^2·h was required to achieve an acceptable amount of surface contamination, and this requirement is used here. However, this requirement should be converted to the required $R_{(\geq 5 \mu m)}$ at the same particle deposition rate level, by use of Formula (E.4):

$$R_{(\geq 5\ \mu m)} = R_{(\geq 20\ \mu m)} \cdot \frac{D_{(20)}}{D_{(5)}} = 200 \cdot \frac{20}{5} = 800 \qquad (E.4)$$

The particle deposition rate requirement at ≥5 µm is, therefore, 800/m^2·h. This requirement can now be converted to the required airborne concentration in terms of the cleanroom classification according to ISO 14644-1.

With Table D.1, it can be seen that this level of air cleanliness is:

— within the extrapolated ISO Class 5 limit (29 particles ≥5 µm per m^3); and

— the ISO 14644-1 cleanliness classification that should be used as the basis of the design requirement.

It should be noted that the relationship of the airborne concentration of particles ≥5 µm to particle deposition rate is dependent on the airborne conditions in the cleanroom and size distribution of the airborne particles. In addition, the calculation of the ISO 14644-1 class can require an extrapolation of the ISO 14644-1 class limits at ≥5 µm. The above method therefore gives an approximate result and should only be used as an aid in the design of cleanroom and clean zones.

E.4.3 Monitoring of the particle deposition rate

The required level of particle deposition rate that is required after the implementation of risk controls should now be monitored during production to ensure that the required limit is maintained over time. Monitoring of the particle deposition rate is discussed in B.2.

Bibliography

[1] ISO 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

[2] ISO 14644-2:2015, *Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

[3] ISO 14644-9:2012, *Cleanrooms and associated controlled environments — Part 9: Classification of surface cleanliness by particle concentration*

[4] IEST-STD-CC1246E:2013, *Product cleanliness levels-applications, requirements, and determination'. Institute of Environmental Sciences and Technology, Arlington Heights, USA*

[5] VCCN Guideline 9. Particle deposition in cleanrooms and associated controlled environments. Vereniging Contamination Control Nederland, The Netherlands, 2014

[6] Whyte W., & Agricola K. Comparison of the loss of macroparticles and MCPs in cleanrooms by surface deposition and mechanical ventilation. *Clean Air and Containment Review*. 2018, Issue 35, pp4-10. Available at: http://eprints.gla.ac.uk/167850/1/167850.pdf

[7] Whyte W., Agricola K., Derks M. Airborne particle deposition in cleanrooms: Deposition mechanisms. *Clean Air and Containment Review*. 2015, Issue 24, pp4-9. Available at: https://eprints.gla.ac.uk/111678/1/111678.pdf

[8] ASTM E2088-06, *Standard Practice for Selecting, Preparing, Exposing, and Analyzing Witness Surfaces for Measuring Particle Deposition in Cleanrooms and Associated Controlled Environments*

[9] ASTM F25/F25M, *Standard Test Method for Sizing And Counting Airborne Particulate Contamination In Cleanrooms and Other Dust-Controlled Areas*

[10] ASTM F50, *Standard Practice for Continuous Sizing and Counting of Airborne Particles in Dust-Controlled areas and Cleanrooms Using Instruments Capable of Detecting Single Sub-Micrometre and Larger Particles*

[11] Agricola K. Real-time particle deposition monitoring of operational cleanroom quality. *Journal of the IEST*. 2016, **59**(1) pp1-13

[12] Agricola K. Practical experiences in practical deposition monitoring. *Clean Air and Containment Review*. 2015, Issue 21, pp4-8

[13] Tovena , Pecault I, Godefroy P, Escoubas L. Qualification testing of an innovative system for monitoring particle contamination fall out. *Sensors and Actuators: A. Physical*. 2017, **253**, pp181-187

[14] ECSS-Q-ST-70-50C. *Space product assurance: Particles contamination monitoring for spacecraft systems and cleanrooms*. European Cooperation for Space Standardization (ECSS) Secretariat, ESA-ESTEC, Requirements and Standards Division, Noordwijk, the Netherlands, 2011

[15] Agricola K. Real time obscuration monitoring. *SPIE Proceedings*. 2016, **9952**: Systems Contamination: Prediction, Control, and Performance. doi:10.1117/12.2237260

[16] Whyte W.M., Eaton T., Lenegan N., Ward S., Agricola K. Calculation of air supply rates and concentration of airborne contamination in non-UDAF-cleanrooms. *European Journal of Parenteral and Pharmaceutical Sciences*. 2017, **22**(4), pp126-138. Available at: https://eprints.gla.ac.uk/157532/1/157532.pdf

[17] Hamberg O. Particle fallout predictions for clean rooms. *The Journal of Environmental Sciences*. 1982, **25**, pp.15-20

[18] PASASURAMAN D.K., KEMPS A.A.M., VEEKE H.P.M., LODEWIJKS G. Prediction model for particle fallout in cleanrooms. *Journal of the IEST.* 2012, **55**(1), pp1-9

[19] WHYTE W., AGRICOLA K., DERKS M. Airborne particle deposition in cleanrooms: Calculation of product contamination and required cleanroom class. *Clean Air and Containment Review.* 2016, Issue 26, pp4-10. Available at: https://eprints.gla.ac.uk/119089/1/119089.pdf

[20] IEC 60812:2018, *Failure modes and effects analysis (FMEA and FMECA)*

[21] VAN , DER , DONCK J.C.J. Contamination Control – A systems approach. In '*Developments in Surface contamination and cleaning, Part 2 Particle deposition, control and removal*'. Elsevier, 2010. ISBN-131-978-1-4377-7830-4

[22] WHYTE W. *Advances in cleanroom technology.* Euromed Communications, 2018. ISBN 978-0-9956666-6-5

[23] AGRICOLA K. Product oriented contamination control (POCC), *Clean Air and Containment Review.* 2015, Issue 24, pp10-17

[24] WHYTE W. Operating a cleanroom: managing the risk from contamination. In '*Cleanroom technology-fundamentals of design, testing and operation (second edition)*'. John Wiley and Sons, Chichester, UK, 2010. ISBN: 978-0-470-74806-0

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