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Cleanrooms and associated controlled environments —

Part 17:
Particle deposition rate applications

Salles propres et environnements maîtrisés apparentés —

Partie 17: Applications de taux de dépôt de particules

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Foreword

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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).

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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):

$$R_D = \frac{C_{f_D} - C_{i_D}}{t_f - t_i} \tag{1}$$

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):

$$N_D = R_D \cdot t \cdot a \tag{2}$$

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 ≥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.

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

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:

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

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

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

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]).

