DRAFT INTERNATIONAL STANDARD

ISO/DIS 14644-17

ISO/TC **209**

Secretariat: **ANSI**

Voting begins on:
2019-10-29

Voting terminates on:
2020-01-21

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

ICS: 13.040.35

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 14644-17:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 Electro technical Commission (IEC) on all matters of electro technical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14644-17 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments* in collaboration with Technical Committee CEN/TC 243, *Cleanroom technology*.

ISO 14644 consists of the following parts, under the general title *Cleanrooms and associated controlled environments*:

Part 1: *Classification of air cleanliness by particle concentration*

Part 2: *Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

Part 3: *Test methods*

Part 4: *Design, construction and start-up*

Part 5: *Operations*

Part 7: *Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

Part 8: *Classification of air cleanliness by chemical concentration*

Part 9: *Classification of surface cleanliness by particle concentration*

Part 10: *Classification of surface cleanliness by chemical concentration*

Part 12: *Specification for monitoring air cleanliness by nanoscale particle concentration*

Part 13: *Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications*

Part 14: *Assessment of suitability for use of equipment by airborne particle concentration*

Part 15: *Assessment of suitability for use of equipment and materials by airborne chemical concentration*

Part 16: *Energy efficiency in cleanrooms and clean air devices*

Attention is also drawn to ISO 14698, Cleanrooms and associated controlled environments — Biocontamination control:

Part 1: *General principles and methods*

Part 2: Evaluation and interpretation of biocontamination data

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[1] considers airborne particles in cleanrooms and classifies their cleanliness by maximum permitted concentrations, and both ISO 14644-9:2012[2] and IEST-STD-CC1246E[3] consider the concentration of surface particles. This ISO standard considers the rate of particle deposition onto cleanroom surfaces and is based on VCCN Guideline 9.[4] The particle deposition rate (PDR) is important, as the probability of contamination by airborne particles onto vulnerable surfaces, such as manufactured products, is directly related to the PDR.

In ISO 14644-3:2019 Test methods,[5] there is an overview of methods for the determination of deposition of particles, larger or equal to 0,1 µm. In this new standard, 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 ISO 5, or cleaner, will 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 these larger particles are not detected in the air by particle counters because of deposition losses in sampling tubes, and the entry to and within particle counters. Large particles cause contamination problems and their presence and potential for deposition onto vulnerable surfaces is best determined by measuring the particle deposition rate (PDR) 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% will be removed from the air by surface deposition, and above 40 µm more than 90% will be deposited.[6] The dominant deposition mechanism of this size of particles has been shown to be gravitational but air turbulence and electrostatic attraction may also cause deposition.[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 will be close to zero with no significant particle deposition. Therefore, it is only in the 'operational' occupancy state that the PDR should be considered.

The PDR 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 PDR required for controlling the airborne contamination of the vulnerable surface obtained. Methods of measuring the PDR in a cleanroom or clean zone are given in this standard. These are used during the operation of the cleanroom to ensure that the required PDR is obtained, and for monitoring the cleanroom and clean zones to demonstrate continuous control of airborne contamination. Monitoring the PDR 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 PDR 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 follows:

$$PDR = (C_f - C_i) / (t - t_i) \quad (1)$$

where,

PDR is the deposition rate per m^2 per hour of particles equal to, or larger than, a considered size in micrometres,

C_f is the final particle surface concentration (number/m^2),

C_i is the initial particle surface concentration (number/m^2),

t is the final time of exposure (hours),

t_i is the initial time of exposure (hours).

In this standard the PDR is applied to cumulative particle sizes (≥ D) and the following notation used:

PDR_D

where, D is the particle size (µm).

If the PDR is determined at a location, 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 the following Formula:

$$\text{Number of deposited particle } (\geq D) = PDR_D \cdot t \cdot a \quad (2)$$

where,

PDR_D is particle deposition rate (number/m^2/hour),

t is the time the surface is exposed to particle deposition (hours),

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 standard also considers particle obscuration rate (POR) of test surfaces exposed in cleanrooms in Annex C. Using the PDR of various particle sizes, the POR of airborne particles depositing onto a surface and obscuring light can be calculated and used in a similar way to the PDR to reduce the risk of surface contamination.

Cleanrooms and associated controlled environments —

Part 17:
Particle deposition rate applications

1 Scope

This part of the ISO 14644 standards gives guidance on the interpretation and application of the results of the measurement of Particle Deposition Rate (PDR) on one, or more vulnerable surfaces in a cleanroom as part of a contamination control programme. It provides some guidance on how to influence the PDR and reduce the risk of particle contamination on vulnerable surfaces.

This standard gives information on how a cleanroom user can use the PDR 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 PDR.

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

This standard does not:

- provide a method to classify a cleanroom with respect to PDR or POR,
- directly consider the deposition of microbe-carrying particles (MCPs), although MCPs 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 document, in whole or in part, is normatively referenced in this standard and is indispensable for its application. The latest edition of the document (including any amendments) applies.

ISO 14644-3, *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. Where a term has been defined in ISO 14644, that definition is normally used.

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 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 that can have a negative impact on the observed vulnerable surface.

3.4
critical location
location where a vulnerable surface is exposed to airborne deposition of particles.

3.5
operational
condition where the cleanroom or clean zone 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 operational occupancy state]

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 circumferential sphere (circle) around a non-spherical particle, or an equivalent diameter determined by the measurement method used.

[SOURCE: ISO 14644-1:2015, 3.2.2 modified]

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

3.8
test surface
surface of specific surface 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 standard to determine the PDR

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

3.9
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 to obtain the PDR 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 Particle deposition rate (PDR)

4.1 General

PDR 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 system that supports the required quality of a cleanroom during operation. The information in the following sections give a method on how the PDR shall be used to establish the correct PDR cleanliness conditions in a cleanroom and associated controlled environments, and is used to demonstrate continued control of these cleanliness conditions.

4.2 PDR for establishing contamination control in a cleanroom

Establishing control of the air cleanliness through use of the PDR is required when a new facility is designed, or when cleanliness requirements are changed in existing facilities. An assessment shall be made of the type of cleanroom manufacturing carried out in the cleanroom. Based on the application, 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 determined. This can be established by consideration of 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 in each vulnerable surface shall be established. This shall be called the 'critical' particle size.

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

3) The maximum number of particles of the critical size that causes contamination problems on each vulnerable surface considered shall be established.

4) Knowing the maximum number of particles of a critical size that is acceptable on each surface, the PDR limits at the critical particle size shall be determined. The use of Annex E shall be considered, which gives information on a method to determine PDR from the maximum number of particles, surface area and time that the vulnerable surface is exposed to airborne contamination.

5) Using the PDR requirements for each vulnerable surface, the maximum allowable PDR, which is the PDR limit (PDRL) shall be obtained from Table 1.