

Cleanrooms and associated controlled environments -
Part 17: Particle deposition rate applications (ISO
14644-17:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 14644-17:2021 sisaldab Euroopa standardi EN ISO 14644-17:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14644-17:2021 consists of the English text of the European standard EN ISO 14644-17:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
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ICS 13.040.35

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English Version

Cleanrooms and associated controlled environments - Part
17: Particle deposition rate applications (ISO 14644-
17:2021)

Salles propres et environnements maîtrisés apparentés
- Partie 17: Applications de taux de dépôt de particules
(ISO 14644-17:2021)

Reinräume und zugehörige Reinraumbereiche - Teil
17: Anwendungen zur Partikelabscheidungsrate (ISO
14644-17:2021)

This European Standard was approved by CEN on 6 January 2021.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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of an identical text or by endorsement, at the latest by August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

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

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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 $>5 \mu\text{m}$ 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 m² 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 m² per hour;
- C_{f_D} is the final particle surface concentration (number per m²) for particles equal to and larger than D (µm);
- C_{i_D} is the initial particle surface concentration (number per m²) 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 (m²).

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/>