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Cleanrooms and associated controlled environments – Part 3: Test methods (ISO 14644-3:2019)

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Denna standard ersätter SS-EN ISO 14644-3:2005, utgåva 1

The European Standard EN ISO 14644-3:2019 has the status of a Swedish Standard. This document contains the official version of EN ISO 14644-3:2019.

This standard supersedes the SS-EN ISO 14644-3:2005, edition 1

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Denna standard är framtagen av kommittén för Renhetsteknik, SIS/TK 108.

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EUROPEAN STANDARD

EN ISO 14644-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2019

ICS 13.040.35

Supersedes EN ISO 14644-3:2005

English Version

Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019)

Salles propres et environnements
maîtrisés apparentés - Partie 3: Méthodes
d'essai (ISO 14644-3:2019)

Reinräume und zugehörige Reinraumbereiche
- Teil 3: Prüfverfahren (ISO 14644-3:2019)

This European Standard was approved by CEN on 24 July 2019.

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European foreword

This document (EN ISO 14644-3:2019) 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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

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The text of ISO 14644-3:2019 has been approved by CEN as EN ISO 14644-3:2019 without any modification.

Introduction

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

This document sets out appropriate test methods for measuring the performance of a cleanroom, a clean zone or an associated controlled environment, including separative devices and controlled zones, together with all associated structures, air treatment systems, services and utilities.

NOTE Not all cleanroom parameter test procedures are shown in this document. The procedure and apparatus for the test carried out for the air cleanliness classes by particle concentration and for macroparticles are provided in ISO 14644-1,^[1] and specifications for monitoring air cleanliness by nanoscale particle concentrations are provided in ISO 14644-12.^[8] The procedures and apparatus to characterize other parameters, of concern in cleanrooms and clean zones used for specific products or processes, are discussed elsewhere in other documents prepared by ISO/TC 209 [for example, procedures for control and measurement of viable materials (ISO 14698 series), testing cleanroom functionality (ISO 14644-4^[3]), and testing of separative devices (ISO 14644-7^[4])]. In addition, other standards can be considered to be applicable. Other cleanliness attribute levels can be determined using ISO 14644-8^[5] (levels of air cleanliness by chemicals), ISO 14644-9^[6] (levels of surface cleanliness by particle concentration) and ISO 14644-10^[7] (levels of surface cleanliness by chemical concentration).

Cleanrooms and associated controlled environments —

Part 3: Test methods

1 Scope

This document provides test methods in support of the operation for cleanrooms and clean zones to meet air cleanliness classification, other cleanliness attributes and related controlled conditions.

Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional airflow and those with non-unidirectional airflow, in three possible occupancy states: as-built, at-rest and operational.

The test methods, recommended test apparatus and test procedures for determining performance parameters are provided. Where the test method is affected by the type of cleanroom or clean zone, alternative procedures are suggested.

For some of the tests, several different methods and apparatus are recommended to accommodate different end-use considerations. Alternative methods not included in this document can be used by agreement between customer and supplier. Alternative methods do not necessarily provide equivalent measurements.

This document is not applicable to the measurement of products or of processes in cleanrooms, clean zones or separative devices.

NOTE This document does not purport to address safety considerations associated with its use (for example, when using hazardous materials, operations and equipment). It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

2 Normative references

There are no normative references in this document.

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 General terms

3.1.1 cleanroom

room within which the number concentration of *airborne particles* (3.2.1) 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* (3.2.4) is specified.

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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]

3.1.2 clean zone

defined space within which the number concentration of *airborne particles* (3.2.1) 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* (3.2.4) 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* (3.1.1) 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]

3.1.3 installation

cleanroom (3.1.1) or one or more *clean zones* (3.1.2), together with all associated structures, air-treatment systems, services and utilities

[SOURCE: ISO 14644-1:2015, 3.1.3]

3.1.4 separative device

equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume

Note 1 to entry: Some industry-specific examples of separative devices are clean air hoods, containment enclosures, glove boxes, isolators and mini-environments.

[SOURCE: ISO 14644-7:2004, 3.17]

3.1.5 resolution

smallest change in a quantity being measured that causes a perceptible change in the corresponding indication

Note 1 to entry: Resolution can depend on, for example, noise (internal or external) or friction. It may also depend on the value of a quantity being measured.

[SOURCE: ISO 14644-1:2015, 3.4.1]

3.1.6 sensitivity

quotient of the change in an indication of a measuring system and the corresponding change in a value of the quantity being measured

3.2 Terms related to airborne particles

3.2.1

airborne particle

solid or liquid object suspended in air, viable or non-viable, sized between 1 nm and 100 µm

Note 1 to entry: For classification purposes, refer to ISO 14644-1:2015, 3.2.1.

3.2.2

count median particle diameter

median particle diameter based on the number of particles

Note 1 to entry: For the count median, one half of the particle number is contributed by the particles with a size smaller than the count median size, and one half by particles larger than the count median size.

3.2.3

mass median particle diameter

median particle diameter based on the particle mass

Note 1 to entry: For the mass median, one half of mass of all particles is contributed by particles with a size smaller than the mass median size, and one half by particles larger than the mass median size.

3.2.4

particle concentration

number of individual particles per unit volume of air

[SOURCE: ISO 14644-1:2015, 3.2.3]

3.2.5

particle size

diameter of a sphere that produces a response, by a given particle-sizing instrument, that is equivalent to the response produced by the particle being measured

Note 1 to entry: For light-scattering airborne-particle instruments, the equivalent optical diameter is used.

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

3.2.6

particle size distribution

cumulative distribution of *particle concentration* ([3.2.4](#)) as a function of *particle size* ([3.2.5](#))

[SOURCE: ISO 14644-1:2015, 3.2.4]

3.2.7

test aerosol

gaseous suspension of solid and/or liquid particles with known and controlled size distribution and concentration

3.3 Terms related to air filters and systems

3.3.1

aerosol challenge

challenging of a filter or an *installed filter system* ([3.3.6](#)) by *test aerosol* ([3.2.7](#))

3.3.2

designated leak

maximum allowable penetration, which is determined by agreement between customer and supplier, through a *leak* ([3.3.8](#)), detectable during *scanning* ([3.3.9](#)) of a filter *installation* ([3.1.3](#)) with light-scattering airborne-particle counters (LSAPC) or *aerosol photometers* ([3.6.2](#))