SLOVENSKI STANDARD
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Čiste sobe in podobna nadzorovana okolja - 3. del: Preskusne metode (ISO/DIS 14644-3:2016)

Cleanrooms and associated controlled environments - Part 3: Test methods (ISO/DIS 14644-3:2016)

Reinräume und zugehörige Reinraumbereiche - Teil 3: Prüfverfahren (ISO/DIS 14644-3:2016)

Salles propres et environnements maîtrisés apparentés - Partie 3: Méthodes d'essai (ISO/DIS 14644-3:2016)

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13.040.35	Brezprašni prostori in povezana nadzorovana okolja	Cleanrooms and associated controlled environments

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Cleanrooms and associated controlled environments —

Part 3:
Test methods

Salles propres et environnements maîtrisés apparentés —

Partie 3: Méthodes d'essai

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

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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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 209.

ISO 14644-3 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

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 6: Vocabulary*

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

— *Part 8: Classification of air cleanliness by chemical concentration (ACC)*

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

— *Part 10: Classification of air cleanliness by chemical concentration*

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Introduction

Cleanrooms and associated controlled environments provide for the control of airborne 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 part of ISO 14644 sets out appropriate test methods for measuring the performance of an installation, a cleanroom or an associated controlled environment.

NOTE Not all cleanroom parameter test procedures are shown in this part of ISO 14644. The procedure and apparatus for the test carried out for the air cleanliness classes by particle concentration are provided in ISO 14644-1, and specifications for monitoring air cleanliness by nanoscale particle concentrations are provided in ISO 14644-12(20XX). 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), testing cleanroom functionality (ISO 14644-4), and testing of separative devices (ISO 14644-7)]. In addition, other standards can be considered to be applicable.

Statements in this part of ISO 14644 reference the standards of ASTM, CEN, DIN, IEST, JACA, JIS and SEMI.

Cleanrooms and associated controlled environments — Part 3: Test methods

1 Scope

This part of ISO 14644 provides test methods in support of the operation for cleanrooms and clean zones to meet air cleanliness classifications and related controlled conditions. Tests for classification of cleanliness are described in ISO 14644-1(classification of air cleanliness by particle concentration and for macroparticles). Other related attribute levels can be determined using ISO 14644-8 (levels of air cleanliness by chemicals), ISO 14644-9 (levels of surface cleanliness by particle concentration) and ISO 14644-10 (levels of surface cleanliness by chemical concentration). Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and those with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational. The test methods, recommend 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 part of ISO 14644 may be used if based on agreement between customer and supplier. Alternative methods do not necessarily provide equivalent measurements.

This part of ISO 14644 is not applicable to the measurement of products or of processes in cleanrooms, clean zones or separative devices.

NOTE: This part of ISO 14644 does not purport to address safety problems associated with its use (for example, when using hazardous materials, operations and equipment). It is the responsibility of the user of this part of ISO 14644 to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

The following referenced documents are indispensable for the application 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 7726:1998, *Ergonomics of the thermal environment — Instruments for measuring physical quantities*

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

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*

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ISO 14644-4:2001, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*

ISO 14644-7:2004, *Cleanrooms and associate controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and minienvironments).*

ISO 14644-8:2013, *Cleanrooms and associate controlled environments — Part 8: Classification of air cleanliness by chemical concentration (ACC).*

ISO 14644-9:2012, *Cleanrooms and associate controlled environments — Part 9: Classification of surface cleanliness by particle concentration.*

ISO 14644-10:2013, Cleanrooms and associated controlled environments — Part 10: Classification of surface cleanliness by chemical concentration.

3 Terms and definitions

3.1 General

3.1.1 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.

[ISO 14644-1:2015, 3.1.1]

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

3.1.3
installation
cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services and utilities
[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.

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.

3.1.6

maximum permissible measurement error

extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring apparatus, or measuring system

Note 1 to entry: Usually the term maximum permissible errors or limit error is used when there are two extreme values.

3.1.7
sensitivity
quotient of the change in an indication of a measuring system and the corresponding change in a value of a quality of the quantity being measured

3.2 Airborne particulates

3.2.1
airborne particle
solid or liquid object suspended in air, viable or non-viable, sized (for the purpose of this part of ISO 14644) between 1 nm and 100 µm

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

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3.2.2
count median particle diameter
CMD
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
MMD
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

[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 discrete-particle light-scattering instruments, the equivalent optical diameter is used.
[ISO 14644-1:2015, 3.2.2]

3.2.6
particle size distribution
cumulative distribution of particle concentration as a function of particle size
[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 Air filters and systems

3.3.1
aerosol challenge
challenging of a filter or an installed filter system by test aerosol

3.3.2
designated leak
maximum allowable penetration, which is determined by agreement between customer and supplier, through a leak, detectable during scanning of an installation with discrete-particle counters or aerosol photometers

3.3.3
dilution system
system wherein aerosol is mixed with particle-free dilution air in a known volumetric ratio to reduce concentration

3.3.4
filter system
system composed of filter, frame and other support system or other housing

3.3.5
final filter
filters in a final position before the air enters the cleanroom or clean zone

3.3.6
installed filter system
filter system mounted in the ceiling, wall, apparatus or duct

3.3.7
installed filter system leakage test
test performed to confirm that the filters are properly installed by verifying that there is absence of bypass leakage in the installation, and that the filters and the grid system are free of defects and leaks

3.3.8
leak
<of air filter system> penetration of contaminants that exceed an expected value of downstream concentration through lack of integrity or defects

3.3.9
scanning
method for disclosing leaks in filters and parts of units, whereby the probe inlet of an aerosol photometer or discrete-particle counter is moved in overlapping strokes across the defined test area

3.3.10
standard leak penetration
leak penetration detected by a discrete-particle counter or aerosol photometer with a standard sample flow- rate when the sampling probe is stationary in front of the leak

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