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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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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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This document was prepared by ISO/TC 209, *Cleanrooms and associated controlled environments*.

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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.

This second edition of ISO 14644-3 cancels and replaces the first edition (ISO 14644-3:2005), which has been technically revised. The main changes compared to the previous edition are as follows:

— Clause B.7 has been simplified and corrected to address concerns over its complexity and noted errors;

— guidance concerning classification of air cleanliness by airborne particle concentration has been moved to 14644-1[1]

— the text of the whole document has been revised or clarified to aid in application.

A list of all parts in the ISO 14644 series can be found on the ISO website.

This corrected version of ISO 14644-3:2019 incorporates the following corrections:

— cross-references have been corrected in Table A.1, B.4.4, C.1, C.4.2 and C.4.3;

— the wording has been changed in B.2.1 a), Table B.2;

— old Figure B.2 has been removed.

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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).

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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.

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

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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]

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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

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[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

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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]

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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

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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)

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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
assembly composed of filter, frame and other support mechanism or other housing

3.3.5
final filter
filter in a final position before the air enters the *cleanroom* (3.1.1) or *clean zone* (3.1.2)

3.3.6
installed filter system
filter system (3.3.4) 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 of the filter *installation* (3.1.3), and that the filters and the grid system are free of defects and *leaks* (3.3.8)

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

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3.3.9
scanning
method for disclosing *leaks* (3.3.8) in filters and parts of units, whereby the probe inlet of an *aerosol photometer* (3.6.2) or a light-scattering airborne-particle counter is moved in overlapping strokes across the defined test area

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3.4 Terms related to airflow and other physical states

3.4.1
air change rate
air exchange rate
rate expressing number of air changes per unit of time and calculated by dividing the volume of air delivered in the unit of time by the volume of the *cleanroom* (3.1.1) or *clean zone* (3.1.2)

3.4.2
measuring plane
cross-sectional area for testing or measuring a performance parameter such as the airflow velocity

3.4.3
non-unidirectional airflow
air distribution where the supply air entering the *cleanroom* (3.1.1) or *clean zone* (3.1.2) mixes with the internal air by means of induction

[SOURCE: ISO 14644-1:2015, 3.2.8]

3.4.4
supply air volume flow rate
air volume per unit of time supplied into a *cleanroom* (3.1.1) or *clean zone* (3.1.2) from *final filters* (3.3.5) or air ducts

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3.4.5
total air volume flow rate
air volume per unit of time that passes through a section of a *cleanroom* (3.1.1) or *clean zone* (3.1.2)

3.4.6
unidirectional airflow
controlled airflow through the entire cross-section of a *cleanroom* (3.1.1) or a *clean zone* (3.1.2) with a steady velocity and airstreams that are considered to be parallel

[SOURCE: ISO 14644-1:2015, 3.2.7]

3.4.7
uniformity of velocity
unidirectional airflow (3.4.6) pattern in which the point-to-point readings of velocity (speed and direction of airflow) are within a defined percentage of the average airflow velocity

3.5 Terms related to electrostatic measurement

3.5.1
discharge time
time required to reduce the voltage to the level, positive or negative, to which an isolated conductive monitoring plate was originally charged

3.5.2
offset voltage
voltage that accumulates on an initially uncharged isolated conductive plate when that plate is exposed to an ionized air environment

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3.5.3
static-dissipative property
capability for reducing electrostatic charge on work or product surface, as a result of conduction or other mechanism to a specific value or nominal zero charge level

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3.5.4
surface voltage level
positive or negative voltage level of electrostatic charging on work or product surface, as indicated by use of suitable apparatus

3.6 Terms related to measuring apparatus and measuring conditions

3.6.1
aerosol generator
apparatus capable of generating particulate matter having appropriate size range (e.g. 0,05 µm to 2 µm) at a constant concentration, which can be produced by thermal, hydraulic, pneumatic, acoustic or electrostatic means

3.6.2
aerosol photometer
light-scattering *airborne particle* (3.2.1) mass concentration measuring apparatus, which uses a forward-scattered-light optical chamber to make measurements

3.6.3
airflow capture hood with measuring device
device with apparatus to completely cover the filter or air diffuser, and collect the air to directly measure the air volume flow rate

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3.6.4
LSAPC
light scattering airborne particle counter
apparatus capable of counting and sizing single *airborne particles* (3.2.1) and reporting size data in terms of equivalent optical diameter

Note 1 to entry: The specifications for a particle counter are given in ISO 21501-4.

[SOURCE: ISO 14644-1:2015, 3.5.1, modified — The term "light scattering discrete airborne particle counter" has been removed. Note 1 to entry has been reworded.]

3.6.5
witness plate
material of defined surface area used in lieu of direct evaluation of a specific surface that is either inaccessible or too sensitive to be handled

3.7 Terms related to occupancy states

3.7.1
as-built
condition where the *cleanroom* (3.1.1) or *clean zone* (3.1.2) is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present

[SOURCE: ISO 14644-1:2015, 3.3.1]

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3.7.2
at-rest
condition where the *cleanroom* (3.1.1) or *clean zone* (3.1.2) is complete with equipment installed and operating in a manner agreed upon, but with no personnel present

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[SOURCE: ISO 14644-1:2015, 3.3.2]

3.7.3
operational
agreed condition where the *cleanroom* (3.1.1) or *clean zone* (3.1.2) 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]

4 Test procedures

4.1 Cleanroom tests

4.1.1 General

ISO 14644-1[1] shall be carried out in order to classify a cleanroom or clean zone by airborne particle concentration. Additional cleanliness attributes should be chosen if required (see Table 1).

NOTE Each standard contains specifications for test methods based on the characteristics of specific attributes, guidance on evaluating the test data and specifications for test apparatus.

Table 1 — Cleanliness attribute tests for cleanrooms and clean zones

General description	Referenced in
Levels of surface cleanliness by particle concentration	ISO 14644-9[6]
Levels of air cleanliness by chemical concentration	ISO 14644-8[5]
Levels of surface cleanliness by chemical concentration	ISO 14644-10[7]
Monitoring air cleanliness by nanoscale particle concentration	ISO 14644-12[8]

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4.1.2 Supporting tests

Table 2 lists other appropriate tests that can be used for measuring the performance of a cleanroom or clean zone installation. These tests may be applied in each of the three designated occupancy states; refer to details in Annex B for suggested applications. These tests may not be all-inclusive. Also, they may not all be required for any given project. Tests and test methods should be selected in a manner agreed between the customer and supplier. Selected tests can also be repeated on a regular basis as part of routine monitoring or periodic testing. Guidelines for the selection of tests and a checklist of tests are given in Annex A. Test methods are outlined in Annex B.

NOTE The test methods described in Annex B are in outline form only. Specific methods can be developed to meet the needs of the particular application.

Table 2 — Supporting tests

Supporting tests	Reference in ISO 14644-3		
	Principle	Procedure	Apparatus
Air pressure difference test	4.2.1	B.1	C.2
Airflow test	4.2.2	B.2	C.3
Airflow direction test and visualization	4.2.3	B.3	C.4
Recovery test	4.2.4	B.4	C.5
Temperature test	4.2.5	B.5	C.6
Humidity test	4.2.6	B.6	C.7
Installed filter system leakage test	4.2.7	B.7	C.8
Containment leak test	4.2.8	B.8	C.9
Electrostatic and ion generator tests	4.2.9	B.9	C.10
Particle deposition test[a]	4.2.10	B.10	C.11
Segregation test	4.2.11	B.11	C.12

NOTE These supporting tests are not presented in order of importance or chronological order. The order in which tests are performed can be based on the requirements of a specific document or after agreement between the customer and supplier.

[a] The particle deposition test can also be considered a test for cleanroom performance in the operational state.

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4.2 Principle

4.2.1 Air pressure difference test

The purpose of the air pressure difference test is to verify the capability of the cleanroom air movement system to maintain the specified pressure differential between the cleanroom and its surroundings. The air pressure difference test should be performed after the cleanroom has met the acceptance criteria for airflow velocity or air volume flow rate, uniformity of velocity and other applicable tests. Details of the air pressure difference test are given in B.1.

4.2.2 Airflow test

This test is performed to measure the supply airflow introduced into both unidirectional and non-unidirectional cleanrooms or clean zones. In unidirectional applications, the supply airflow velocity can be measured with individual point readings to allow for the measurement of velocity and determination of uniformity of velocity. The average of the individual velocity point readings may be used to calculate the supply airflow volume and air change rate (air changes per hour). In non-unidirectional applications, individual velocity point readings are typically not required as uniformity of velocity is generally not necessary. In these cases, airflow volume readings may be measured directly and then used in calculating the air change rate (air changes per hour) for the cleanroom or clean zone. Test procedures for the airflow test are given in B.2.

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4.2.3 Airflow direction test and visualization

The purpose of this test is to demonstrate that the airflow direction and its uniformity of velocity conform to the design and performance specifications. The airflow direction test can be conducted in the at-rest state to determine the basic cleanroom airflow patterns and can be repeated in the operational state simulating actual operations. Procedures for this test are given in B.3.

4.2.4 Recovery test

The recovery test is performed to determine whether the cleanroom or clean zone is capable of returning to a specified cleanliness level within a finite time, after being exposed briefly to a source of airborne particulate challenge. This test is not recommended for unidirectional airflow. The procedure for this test is given in B.4. When an artificial aerosol is used, the risk of residue contamination of the cleanroom or clean zone should be considered.

4.2.5 Temperature test

The purpose of this test is to verify the air temperature levels are within the control limits over the time period specified by the customer for the area being tested. Procedures for these tests are given in B.5.

4.2.6 Humidity test

The purpose of this test is to verify moisture (expressed as relative humidity or dew point) levels are within the control limits over the time period specified by the customer for the area being tested. Procedures for these tests are given in B.6.

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4.2.7 Installed filter system leakage tests

These tests are performed to confirm that the final high efficiency air filter system is properly installed by verifying the absence of bypass leakage in the air filter installation, and that the filters are free of defects (small holes and other damage in the filter medium, frame, seal and leaks in the filter bank framework). These tests are not used to determine the efficiency of the filter medium. The tests are performed by introducing an aerosol challenge upstream of the filters and scanning downstream of the filters and support frame or sampling in a downstream duct. Leak detection methods are given in B.7.

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4.2.8 Containment leak test

This test is performed to determine if there is intrusion of unfiltered air into the cleanroom or clean zone(s) from outside the cleanroom or clean zone enclosure(s) through joints, seams, doorways and pressurized ceilings. The procedure for this test is given in B.8.

4.2.9 Electrostatic and ion generator tests

The purpose of these tests is to evaluate electrostatic voltage levels on objects, static-dissipative properties of materials and the performance of ion generators (i.e. ionizers) used for electrostatic control in cleanrooms or clean zones. Electrostatic testing is performed to evaluate the electrostatic voltage level on work and product surfaces, and the static dissipative properties of floors, workbench tops, etc. The ion generator test is performed to evaluate the ionizer performance in eliminating static charges on surfaces. Procedures for these tests are given in B.9.

4.2.10 Particle deposition test

The purpose of this test is to verify the quantity and size of particles deposited from the air in the cleanroom onto a surface over an agreed period of time. Procedures for this test are given in B.10.

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4.2.11 Segregation test

The purpose of this test is to assess the separation effectiveness achieved by a specific airflow, challenging the lesser classified area with particles and determining the particle concentration in the protected area at the other side of the segregation. Procedures for this test are given in B.11.

5 Test reports

The result of each test shall be recorded in a test report, and the test report shall include the following information:

a) the name and address of the testing organization, and the date on which the test was performed;

b) a reference to this document (ISO 14644-3:2019);

c) clear identification of the physical location of the cleanroom or clean zone tested (including reference to adjacent areas if necessary), and specific designations for coordinates of all sampling locations;

d) the specified designation criteria for the cleanroom or clean zone, including the ISO classification, the relevant occupancy state(s), and the considered particle size(s);

e) the details of the test method used, with any special conditions relating to the test or departures from the test method, and identification of the test apparatus and its current calibration certificate;

f) the test result, including data reported as specifically required in the relevant clause of Annex B, and a statement regarding compliance with the claimed designation;

g) any other specific requirements defined relevant to the clause of Annex B for particular tests.

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