INTERNATIONAL STANDARD

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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.

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

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

— *Part 1: Classification of air cleanliness*

— *Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*

— *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 airborne molecular contamination*

The following part is under preparation:

— *Part 6: Vocabulary*

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 test methods that may be used for the purpose of characterizing a cleanroom as described and specified in other parts of ISO 14644.

NOTE Not all cleanroom parameter test procedures are shown in this part of ISO 14644. 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

WARNING — The use of this part of ISO 14644 may involve hazardous materials, operations and equipment. This part of ISO 14644 does not purport to address all of the safety problems associated with its use. 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.

1 Scope

This part of ISO 14644 specifies test methods for designated classification of airborne particulate cleanliness and for characterizing the performance of cleanrooms and clean zones. 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. 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 or separative devices.

2 Normative references

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 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 14644-2:2000, *Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 General

3.1.1
cleanroom
room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation and retention of particles inside the room, and in which other relevant parameters, e.g. temperature, humidity and pressure, are controlled as necessary

[ISO 14644-1:1999, 2.1.1]

3.1.2
clean zone
dedicated space in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation and retention of particles inside the zone, and in which other relevant parameters, e.g. temperature, humidity and pressure, are controlled as necessary

NOTE This zone may be open or enclosed, and may or may not be located within a cleanroom.

[ISO 14644-1:1999, 2.1.2]

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

[ISO 14644-1:1999, 2.1.3]

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

3.2 Airborne particle measurement

3.2.1
aerosol generator
instrument capable of generating particulate matter having appropriate size range (e.g. 0,05 µm to 2 µm) at a constant concentration, which may be produced by thermal, hydraulic, pneumatic, acoustic or electrostatic means

3.2.2
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 For classification purposes, refer to ISO 14644-1:1999, 2.2.1.

3.2.3
count median particle diameter
CMD
median particle diameter based on the number of particles

NOTE 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.

3.2.4
macroparticle
particle with an equivalent diameter greater than 5 µm

[ISO 14644-1:1999, 2.2.6]

3.2.5
M descriptor
measured or specified concentration of macroparticles per cubic metre of air, expressed in terms of the equivalent diameter that is characteristic of the measurement method used

NOTE The M descriptor may be regarded as an upper limit for the averages at sampling locations (or as an upper confidence limit, depending upon the number of sampling locations used to characterize the cleanroom or clean zone). M descriptors cannot be used to define airborne particulate cleanliness classes, but they may be quoted independently or in conjunction with airborne particulate cleanliness classes.

[ISO 14644-1:1999, 2.3.2]

3.2.6
mass median particle diameter
MMD
median particle diameter based on the particle mass

NOTE 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.

3.2.7
particle concentration
number of individual particles per unit volume of air

[ISO 14644-1:1999, 2.2.3]

3.2.8
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 For discrete-particle-counting, light-scattering instruments, the equivalent optical diameter is used.

[ISO 14644-1:1999, 2.2.2]

3.2.9
particle size distribution
cumulative distribution of particle concentration as a function of particle size

[ISO 14644-1:1999, 2.2.4]

3.2.10
test aerosol
gaseous suspension of solid and/or liquid particles with known and controlled size distribution and concentration

3.2.11
U descriptor
measured or specified concentration in particles per cubic metre or air, including the ultrafine particles

NOTE The U descriptor may be regarded as an upper limit for the averages at sampling locations (or as an upper confidence limit, depending upon the number of sampling locations used to characterize the cleanroom or clean zone). U descriptors cannot be used to define airborne particulate cleanliness classes, but they may be quoted independently or in conjunction with airborne particulate cleanliness classes.

[ISO 14644-1:1999, 2.3.1]

3.2.12
ultrafine particle
particle with an equivalent diameter less than 0,1 µm

[ISO 14644-1:1999, 2.2.5]

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

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

NOTE Penetration is the ratio of the particle concentration downstream of the filter to the concentration upstream.

3.4 Airflow and other physical states

3.4.1
air exchange rate
rate of air exchange expressed as 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 space

3.4.2
average airflow rate
averaged volume of air per unit of time, to determine the air exchange rate in a cleanroom or clean zone

NOTE Airflow rate is expressed in cubic metres per hour (m^3/h).

3.4.3
measuring plane
cross-sectional area for testing or measuring a performance parameter such as the airflow velocity

3.4.4
non-unidirectional airflow
air distribution where the supply air entering the clean zone mixes with the internal air by means of induction

[ISO 14644-4:2001, 3.6]

3.4.5
supply airflow rate
air volume supplied into an installation from final filters or air ducts in unit of time

3.4.6
total airflow rate
air volume that passes through a section of an installation in unit of time

3.4.7
unidirectional airflow
controlled airflow through the entire cross-section of a clean zone with a steady velocity and approximately parallel streamlines

NOTE This type of airflow results in a directed transport of particles from the clean zone.

[ISO 14644-4:2001, 3.11]

3.4.8
uniformity of airflow
unidirectional airflow pattern in which the point-to-point readings of velocities are within a defined percentage of the average airflow velocity

3.5 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 will accumulate upon an initially uncharged isolated conductive plate when that plate is exposed to an ionized air environment

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

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 Measuring apparatus and measuring conditions

3.6.1
aerosol photometer
light-scattering airborne particle mass concentration measuring apparatus, which uses a forward-scattered-light optical chamber to make measurements

3.6.2
anisokinetic sampling
sampling condition in which the mean velocity of the air entering the sample probe inlet is significantly different from the mean velocity of the unidirectional airflow at that location

3.6.3
cascade impactor
sampling device, which collects particles from an aerosol using the principle of impaction upon a series of collector surfaces

NOTE Each successive collector surface is exposed to an aerosol stream flowing at a higher velocity than was the previous one, thus allowing collection of smaller particles than the previous one.

3.6.4
condensation nucleus counter
CNC
instrument that is capable of enlarging ultrafine particles by means of condensation for subsequent counting using optical particle counting techniques

3.6.5
counting efficiency
ratio of the reported concentration of particles in a given size range to the actual concentration of such particles

3.6.6
differential mobility analyzer
DMA
instrument for measuring the particle size distribution, based on the electrical mobility of particles

3.6.7
diffusion battery element
individual component from a multi-stage particle size cutoff device, operating on the principle of diffusion to remove smaller particles from an aerosol stream

3.6.8
discrete-particle counter
DPC
instrument having a means of displaying and recording the count and size of discrete particles (with a size discrimination) for specific air volume

3.6.9
false count
background noise count
zero count
count produced by a discrete-particle counter (DPC) due to internal or external unwanted electronic signal when no particles exist

3.6.10
flowhood with flowmeter
device with apparatus to directly measure the airflow volume at each final filter or air diffuser in an installation, set up to completely cover the filter or diffuser

3.6.11
iso-axial sampling
sampling condition in which the direction of the airflow into the sample probe inlet is the same as that of the unidirectional airflow being sampled

3.6.12
isokinetic sampling
sampling condition in which the mean velocity of the air entering the sample probe inlet is the same as the mean velocity of the unidirectional airflow at that location

3.6.13
particle size cutoff device
device capable of removing particles smaller than those of interest that is attached to the inlet of a DPC or CNC

3.6.14
threshold size
selected minimum particle size chosen for measuring a concentration of particles larger than or equal to that size

3.6.15
time-of-flight particle size measurement
measurement of aerodynamic particle diameter determined by the time required for travelling the distance of two fixed planes

NOTE This measurement utilizes the particle velocity shift caused when a particle is introduced into the flow field with different velocity.

3.6.16
virtual impactor
instrument to separate the particle sizing by inertial force to collide on the hypothetical (virtual) surface

NOTE Large particles pass through the surface into a stagnant volume and small particles deflected with the bulk of the original airflow.

3.6.17
witness plate
contamination-sensitive 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 Occupancy states

3.7.1
as-built
condition where the installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present

[ISO 14644-1:1999, 2.4.1]

3.7.2
at-rest
condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present

[ISO 14644-1:1999, 2.4.2]

3.7.3
operational
condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon

[ISO 14644-1:1999, 2.4.3]

4 Test procedures

4.1 Cleanroom tests

4.1.1 Required test

An airborne particle count test (see Table 1) shall be carried out in order to classify an installation in accordance with ISO 14644-1, at the time intervals specified in ISO 14644-2.

Table 1 — Required test for installation

Required tests	Reference in ISO 14644-3:2005			Referenced in
	Principle	Procedure	Apparatus	
Airborne particle count for classification and test measurement of cleanrooms and clean air devices	4.2.1	B.1	C.1	ISO 14644-1 and ISO 14644-2

4.1.2 Optional tests

Table 2 lists other tests appropriate for testing of an installation. These tests can be applied in each of the three designated occupancy states. These tests may not be all-inclusive, nor may all of the tests be required for any given certification 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 a routine facility monitoring program (see ISO 14644-2). Guidelines for the selection of tests and a checklist of tests are given in Annex A. Test methods are outlined in Annex B.

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

Table 2 — Optional tests for installation

Optional tests	Reference in ISO 14644-3:2005			Referenced in
	Principle	Procedure	Apparatus	
Airborne particle count for ultrafine particles	4.2.1	B.2	C.2	ISO 14644-1
Airborne particle count for macroparticles	4.2.1	B.3	C.3	ISO 14644-1
Airflow test[a]	4.2.2	B.4	C.4	ISO 14644-1 and ISO 14644-2
Air pressure difference test[a]	4.2.3	B.5	C.5	ISO 14644-1 and ISO 14644-2
Installed filter system leakage test	4.2.4	B.6	C.6	ISO 14644-2
Airflow direction test and visualization	4.2.5	B.7	C.7	ISO 14644-2
Temperature test	4.2.6	B.8	C.8	ISO 7726
Humidity test	4.2.6	B.9	C.9	ISO 7726
Electrostatic and ion generator test	4.2.7	B.10	C.10	
Particle deposition test	4.2.8	B.11	C.11	
Recovery test	4.2.9	B.12	C.12	ISO 14644-2
Containment leak test	4.2.10	B.13	C.13	ISO 14644-1 and ISO 14644-2

[a] This is a required test based on ISO 14644-2. These optional tests are not presented in order of importance. The order in which tests should be performed may be based upon the requirements of a specific document or after agreement between the customer and supplier.

4.2 Principle

4.2.1 Airborne particle count

This test is performed to determine air cleanliness and may consist of three parts as follows:

a) classification test (see B.1);

b) ultrafine particle test (optional) (see B.2);

c) macroparticle test (optional) (see B.3).

Tests b) and c) may be used for descriptive purposes or as the basis for a specified requirement, but cannot be used for classification purposes.

4.2.2 Airflow test

This test is performed to determine the supply airflow rate in a non-unidirectional cleanroom and the air velocity distribution in a unidirectional cleanroom. Typically, either airflow velocity or airflow rate testing will be performed, and results will be required in only one format: average velocity, average airflow rate or total airflow rate. Total airflow rate may, in turn, be used to determine the air exchange rate (air changes per hour) for a non-unidirectional installation. The air velocity will be determined in unidirectional cleanrooms. Test procedures for the airflow test are given in B.4.