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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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

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.

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.

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)

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

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

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

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

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 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

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]

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

[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]

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.

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.

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.

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.

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.

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.

Annex A
(informative)

Choice of supporting tests and checklist

A.1 General

Special care should be taken when determining the sequence for carrying out tests for cleanroom, clean zone or controlled zone performance.

The selection and sequence of tests should be determined between customer and supplier and should detect noncompliance at the earliest stage possible and not compromise other tests in the sequence.

A.2 Test checklist

Table A.1 provides a checklist of tests and apparatus.

Table A.1 — Checklist of supporting tests

Selection of test procedure and sequence[a]	Test procedure	Test procedure reference	Selection of test apparatus[b]	Test apparatus	Apparatus reference	Comments
	Air pressure difference	B.1		Electronic micromanometer	C.2.2	
				Inclined manometer	C.2.3	
				Mechanical differential pressure gauge	C.2.4	
	Airflow	B.2			C.3	
	Uniformity of velocity within the cleanroom or clean zone (for unidirectional airflow)	B.2.2.2		Thermal anemometer	C.3.1.2	
				Three-dimensional ultrasonic anemometer, or equivalent	C.3.1.3	
				Vane-type anemometer	C.3.1.4	
				Tube array	C.3.1.6	
	Supply airflow velocity (for unidirectional airflow)	B.2.2.3		Thermal anemometer	C.3.1.2	
				Three-dimensional ultrasonic anemometer, or equivalent	C.3.1.3	
				Vane-type anemometer	C.3.1.4	
				Tube array	C.3.1.6	
	Supply air volume flow rate measured by filter face velocity (for unidirectional airflow)	B.2.2.4		Thermal anemometer	C.3.1.2	
				Three-dimensional ultrasonic anemometer, or equivalent	C.3.1.3	
				Vane-type anemometer	C.3.1.4	
				Tube array	C.3.1.6	

Table A.1 *(continued)*

Selection of test procedure and sequence[a]	Test procedure	Test procedure reference	Selection of test apparatus[b]	Test apparatus	Apparatus reference	Comments
	Supply air volume flow rate in air ducts (for unidirectional airflow)	B.2.2.5		Orifice meter	C.3.2.3	
				Venturi meter	C.3.2.4	
				Pitot-static tubes and manometer	C.3.1.5	
				Thermal anemometer	C.3.1.2	
	Supply air volume flow rate measured at the inlet (for non- unidirectional airflow installation)	B.2.3.2		Airflow capture hood with measuring device	C.3.2.2	
	Supply air volume flow rate calculated from filter face velocity (for non-unidirectional airflow i)	B.2.3.3		Thermal anemometer	C.3.1.2	
				Three-dimensional ultrasonic anemometer, or equivalent	C.3.1.3	
				Vane-type anemometer	C.3.1.4	
	Supply air volume flow rate in air ducts (for non-unidirectional airflow)	B.2.3.4		Orifice meter	C.3.2.3	
				Venturi meter	C.3.2.4	
				Pitot-static tubes and manometer	C.3.1.5	
				Thermal anemometer	C.3.1.2	
	Airflow direction and visualization	B.3		Tracers	C.4.4.1	
				Thermal anemometer	C.4.2	
				Three-dimensional ultrasonic anemometer, or equivalent	C.4.3	
				Aerosol generator	C.4.4	
				Ultrasonic nebulizer	C.4.4.2	
				Fog generator	C.4.4.3	
	Recovery	B.4		Light-scattering airborne-particle counter (LSAPC	C.5.1	
				Aerosol generator	C.5.2	
				Aerosol source substances	C.5.3	
				Dilution system, equipment	C.5.4	
				Thermometer	C.6	
	Temperature	B.5		Expansion Thermometer	C.6 a)	
				Electrical Thermometer	C.6 b)	
				Thermomanometers	C.6 c)	
	Humidity	B.6		Dewpoint hygrometer	C.7 a)	
				Electrical conductivity variation hygrometer	C.7 b)	

Table A.1 *(continued)*

Selection of test procedure and sequence[a]	Test procedure	Test procedure reference	Selection of test apparatus[b]	Test apparatus	Apparatus reference	Comments
	Installed filter system leakage	B.7			C.8	
	Installed filter system leakage scan test with an aerosol photometer	B.7.2		Aerosol photometer	C.8.1	
				Aerosol generator	C.8.3	
				Test aerosol source substances	C.8.4	
	Installed filter system leakage scan test with a LSAPC	B.7.3		Light-scattering airborne- particle counter (LSAPC)	C.8.2	
				Aerosol generator	C.8.3	
				Test aerosol source substances	C.8.4	
				Dilution system, equipment	C.8.5	
	Overall leak test of filters mounted in ducts or air-handling units	B.7.4		Aerosol photometer	C.8.1	
				Light-scattering airborne- particle counter (LSAPC)	C.8.2	
				Aerosol generator	C.8.3	
				Test aerosol source substances	C.8.4	
				Dilution system, equipment (LSAPC method only)	C.8.5	
	Containment leak	B.8			C.9	
	Light-scattering airborne-particle counter (LSAPC) method	B.8.2.1		Light-scattering airborne-particle counter (LSAPC)	C.9.1	
				Aerosol generator	C.9.2	
				Test aerosol source substances	C.9.3	
				Dilution system, equipment	C.9.4	
	Aerosol photometer method	B.8.2.2		Aerosol generator	C.9.2	
				Test aerosol source substances	C.9.3	
				Aerosol photometer	C.9.5	
	Electrostatic and ion generator	B.9			C.10	
	Electrostatic	B.9.2.1		Electrostatic voltmeter	C.10.1	
				High resistance ohm-meter	C.10.2	
				Charged plate monitor	C.10.3	

Table A.1 *(continued)*

Selection of test procedure and sequence[a]	Test procedure	Test procedure reference	Selection of test apparatus[b]	Test apparatus	Apparatus reference	Comments
	Ion generator	B.9.2.2		Electrostatic voltmeter	C.10.1	
				High resistance ohmmeter	C.10.2	
				Charged plate monitor	C.10.3	
	Particle deposition	B.10		Witness plate material	C.11.1	
				Wafer surface scanner	C.11.2	
				Particle fallout aerosol photometer	C.11.3	
				Surface particle counter	C.11.4	
				Particle deposition meter	C.11.5	
				Optical particle deposition monitor	C.11.6	
	Segregation test	B.11		Light-scattering airborne-particle counter (LSAPC)	C.12.1	
				Aerosol generator	C.12.2	
				Test aerosol source substances	C.12.3	
				Dilution system, equipment	C.12.4	

[a] In the boxes of column 1, test planners can number the selected test methods according to the test sequence.

[b] In the fourth column, test planners can select test apparatus according to the test method selected.

A.3 Planning for testing and verification

As a minimum, testing should be carried out:

a) in connection with classification according to ISO 14644-1;

b) at verification during start-up;

c) at verification after failures have been identified and rectified;

d) at verification after modification;

e) during periodic testing.

A risk assessment should be performed to establish the appropriate intervals for periodic testing.

Monitoring data, trend and test result should be used to confirm and, if appropriate, adjust time intervals for the selected tests.

Annex B
(informative)

Supporting test methods

B.1 Air pressure difference test

B.1.1 General

The purpose of this test is to verify the capability of the complete installation to maintain the specified pressure difference between the cleanroom and its surroundings, and between separate cleanrooms and clean zones within the installation.[18] This test is applicable in each of the three designated occupancy states, and can also be repeated on a regular basis as part of a routine facility monitoring program as described in ISO 14644-2[2].

B.1.2 Procedure for air pressure difference test

It is recommended that the following items are confirmed before starting the measurement of differential pressure between rooms or between rooms and outside areas:

- values and acceptable range of differential pressure between rooms should be defined;
- supply air volume and balancing of the air handling unit supplies are within specifications;
- cleanroom components that could impact the differential pressure between rooms such as doors, windows, pass through, etc. should be closed. Permanent openings should be kept open during the test;
- the air handling system has been operated and the conditions have been stabilized;
- extraction systems should be operating as agreed and specified.

The pressure differences between each individual cleanroom, clean zone and the connected adjacent room(s) should be measured.

This will include measurement of the pressure difference between (a) classified room(s) connected to the non-classified surrounding environment.

To avoid possible erroneous readings, the following should be considered:

a) installation of permanent measuring points;

b) measurements in the cleanroom and clean zone should not be taken near supply air inlets, return air outlets, air movement devices, doors and other localized high air velocity areas that may influence the local pressure at the measuring point;

c) when the measured differential pressure is lower than an agreed value, direction of flow between rooms should be confirmed by flow visualization methods.

B.1.3 Apparatus for air pressure difference test

Apparatus descriptions and measurement specifications are provided in C.2. An electronic micromanometer, inclined manometer, or mechanical differential pressure gauge can be used.

The apparatus should have a valid calibration certificate.

B.1.4 Test reports

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

a) type of tests and measurements, and measuring conditions;

b) type designations of each measuring apparatus and apparatus used and its calibration status;

c) cleanliness classes of the rooms considered;

d) measuring point locations, when required the reference point location;

e) occupancy state(s).

B.2 Airflow test

B.2.1 General

The purpose of these tests is to measure airflow velocity and uniformity, and supply air volume flow rate in cleanrooms and clean zones. Measurement of velocity distribution is necessary in unidirectional airflow cleanrooms and clean zones, and supply air volume flow rate in non-unidirectional cleanrooms. Measurement of supply air volume flow rate is carried out to ascertain the air volume supplied to the cleanroom or clean zone per unit of time. The supply air volume flow rate is measured either downstream of final filters or in air supply ducts; both methods rely upon measurement of velocity of air passing through a known area, the air volume flow rate being the product of velocity and area. The choice of procedure should be agreed between customer and supplier.

When measuring airflow velocity, the following conditions should be considered carefully:

a) probe direction should be chosen appropriately with consideration of the airflow direction;

b) measurement should be conducted during sufficient time for repeatable readings and the average velocity or air volume flow rate should be recorded.

B.2.2 Procedure for unidirectional airflow testing

B.2.2.1 General

The velocity of the unidirectional flow determines the performance of a unidirectional cleanroom. The velocity can be measured close to the face of the terminal supply filters, or within the room. This is done by defining the measuring plane perpendicular to the supply airflow and dividing it into measuring points (grid cells) of equal area[18].

B.2.2.2 Supply airflow velocity

The airflow velocity should be measured at approximately 150 mm to 300 mm from the filter face or entry plane.

The number of measuring points (grid cells) is highly dependent upon the instrumentation used to perform the measurements, configuration of room infrastructure, location or process equipment and the design of the installed filter cell. The minimum number of measuring points (grid cells) should be determined by Formula (B.1):

$$N = \sqrt{10 \times A} \qquad \text{(B.1)}$$

where

N is the minimum number of measuring points (grid cells; N should be rounded up to a whole number);

A is the measured area in m^2.

Where the average velocity is required for a zone with unidirectional airflow, the average velocity is calculated from Formula (B.2):

$$V_a = (\sum V_n) / N \qquad \text{(B.2)}$$

where

V_a is the average velocity in m/s;

$\sum V_n$ is the sum of all the measured velocities (V_n) in m/s;

V_n is the measured velocity at each of the grid cell centres in m/s;

N is the number of locations at which the velocities (V_n) were measured.

At least one point should be measured for each filter outlet or fan-filter unit.

If the measured data is to be used to determine airflow volume flow rate as in B.2.2.4 or uniformity of velocity as in B.2.2.3, then it can be advantageous to increase the number of measuring points (grid cells).

For smaller areas, it can be necessary to increase the number of measuring points (grid cells) to improve the likelihood of detection of uneven airflow velocities.

The measuring time at each position should be sufficient to ensure a repeatable reading. Time-averaged values of measured velocities should be recorded for multiple locations.

NOTE 1 If the supply airflow velocity is measured too close to the source, there is a risk of measurement error due to variable airflow distribution. If the supply airflow velocity is measured too far from the filter face, the measurement reading can be compromised.

NOTE 2 A temporary barrier can be used to exclude disturbances to the unidirectional airflow.

B.2.2.3 Uniformity of velocity within the cleanroom or clean zone

The uniformity of velocity can be measured according to B.2.2.2 or as agreed between customer and supplier.

NOTE When production apparatus and workbenches are installed, it is important to confirm that significant airflow variations do not occur.

The data to be used to determine the uniformity of velocity and maximum deviation, i.e. the velocity and its variation, should be agreed between customer and supplier.

The standard deviation and mean average should be calculated from the velocity readings and the uniformity of velocity, U_V, obtained with Formula (B.3):

$$U_V = [1 - (\sigma / V_a)] \times 100 \qquad \text{(B.3)}$$

where

σ is the standard deviation;

V_a is the average velocity.

The maximum deviation of velocity, D_{max}, is calculated with Formula (B.4):

$$D_{\mathrm{max}} = [(V_d - V_a) / V_a] \times 100 \tag{B.4}$$

where

s_{max} is the maximum deviation in %;

V_a is the average velocity;

V_d is the reading with most variance from the average.

B.2.2.4 Supply air volume flow rate calculated from the velocity measurement

The results of the airflow velocity test carried out in accordance with B.2.2.2 can be used to calculate the total supply air volume flow rate with Formula (B.5):

$$Q = \sum(V_{\mathrm{n}} \times A_{\mathrm{c}}) \tag{B.5}$$

where

A_{c} is the cell area which is defined as the free area of the media divided by the number of measuring points (grid cells) in m^2;

Q is the total air volume flow rate in m^3/s;

V_{n} is the airflow velocity at each cell centre in m/s;

$\sum$ is the summation for all cells.

NOTE The accuracy of the air volume flow rate, when calculated using this method can be influenced by many factors, such as; choice of test apparatus, choice of measuring locations, number of measuring points (grid cells), distance from filter face and calculation of open cell area.

B.2.2.5 Supply air volume flow rate calculated from velocity measurement in air ducts

Supply air volume flow rate in ducts may be determined by using apparatus such as orifice meters, Venturi meters, pitot static tubes and anemometers.

In cases of the measurement by pitot static tubes and manometers or anemometers (thermal or vane type) for a rectangular duct, the measuring plane in the duct should be divided into measuring points (grid cells) of equal areas, and then the airflow velocity should be measured at the centre of each cell. The number of measuring points (grid cells) is agreed between customer and supplier. The air volume flow rate should be evaluated in the same way as defined in B.2.2.4. For a circular duct, the air volume flow rate by pitot static tubes may be determined by the procedure as typically described in ISO 5167-5[24].

NOTE When measuring supply air volume flow rate, there can be differences between the measuring methods by filter face velocity and measurement in the air duct.

B.2.3 Procedure for non-unidirectional airflow test

B.2.3.1 General

In some cases, measurement of supply airflow velocity from individual outlets is necessary to determine the air volume flow rate from each outlet[18].

B.2.3.2 Supply air volume flow rate measured using a capture hood

Because of the effect of local airflow turbulence and jet velocities issuing from an outlet, use of an airflow capture hood that captures all of the air issuing from each final filter or supply diffuser is recommended. The supply air volume flow rate is measured using an airflow capture hood with a measuring device, or the air velocity of the air exiting from an airflow capture hood multiplied by the effective area. The opening of airflow capture hood should be placed completely over the entire filter or diffuser, and the face of the hood should be seated against a flat surface to prevent air bypass and inaccurate readings. When an airflow capture hood with measuring device is adopted, the air volume flow rate at each final filter or supply diffuser should be measured directly at the discharge end of the hood.

The accuracy of the airflow capture hood should be verified to show that it gives accurate results for the type of air outlet being measured, and a correction factor should be applied if the results are not accurate. The correction factor is related to the flow. It corresponds to an in situ check and is based on the difference between the reference measurement in air ducts and the air outlet.

Also, in case an air outlet is fitted with (swirl) diffusers the airflow capture hood can be adapted for the flow type of the diffuser.

B.2.3.3 Supply air volume flow rate calculated by velocity measurement

Evaluation of the supply air volume flow rate without an airflow capture hood may be done with an anemometer downstream of each final filter. The supply air volume flow rate is determined from the airflow velocity multiplied by the corrected (free) area of exit. A temporary barrier may be used to exclude disturbances to the unidirectional airflow.

For the number of measuring points (grid cells) and the calculation of supply air volume flow rate, refer to B.2.2.2 and B.2.2.4, respectively.

If it is impossible to divide the plane into measuring points (grid cells) of equal areas, the average air velocity weighted by area may be substituted.

The accuracy of the air volume flow rate, when calculated using this method can be in influenced by many factors, such as; choice of test apparatus, choice of measuring locations, number of measuring points (grid cells), distance from filter face and calculation of open cell area. Consideration should be given to these potential variations when performing this test.

B.2.3.4 Supply air volume flow rate calculated by velocity measurement in air ducts

Supply air volume flow rate in air ducts should be determined in the same way as defined in B.2.2.5.

B.2.4 Apparatus for airflow tests

Descriptions and measurement specifications of apparatus are provided in C.3. For airflow velocity measurements, ultrasonic anemometers, thermal anemometers, vane-type anemometers, or their equivalent, can be used.

For supply air volume flow rate measurements, airflow capture hood, orifice meters, Venturi meters, pitot static tubes, averaging tube array and manometers, or their equivalent, can be used.

Airflow velocity measurements should be made with apparatus that is not affected by point-to-point velocity variation over small distances, e.g. a thermal anemometer can be used if small grid divisions are selected and additional measuring points (grid cells) are used. On the other hand, a vane anemometer can be used if it is sensitive enough and large enough to measure average air velocity over a range of variation.

The apparatus chosen should have a valid calibration certificate.

B.2.5 Test reports

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

a) type of tests and measurements, and measuring conditions;

b) type designations of each measuring apparatus used and its calibration status;

c) measuring locations and the distance from the filter face;

d) occupancy state(s);

e) result of measurement;

f) other data relevant for measurement.

B.3 Airflow direction test and visualization

B.3.1 General

The purpose of airflow direction test and visualization is to demonstrate that the airflow direction and its uniformity of velocity conform to the design and performance specifications.

NOTE 1 Computational Fluid Dynamics (CFD) used as a predictive or analytical tool is not considered in this document.

NOTE 2 Tracer thread methods may not give a true indication of the direction of airflow due to the tracer material’s characteristics, e.g. weight of the thread.

B.3.2 Methods

The airflow direction test and visualization can be performed by the following four methods:

a) tracer thread method;

b) tracer injection method;

c) airflow visualization method by image processing techniques;

d) airflow visualization method by the measurement of velocity distribution.

By methods a) and b), airflow in the cleanroom or clean zone is actually visualized by the use of fibre tracer thread, or tracer particles. Devices, such as video cameras, record the profiles. The fibre tracer thread or tracer particles should not be a source of contamination and should follow the airflow profile accurately. Other apparatus such as a tracer particle generator, and high intensity light source may be used for these methods.

Method c) is used to demonstrate quantitatively the airflow velocity distributions in the cleanroom or clean zone. The technique is based on tracer particle image processing techniques using computers.

Care should be taken to ensure that the personnel undertaking the test do not interfere with the airflow patterns being investigated.

NOTE 1 The airflow is affected by other parameters such as air pressure difference, air velocity, and temperature.

NOTE 2 Appropriate airflow visualisation techniques best assess the effectiveness of air distribution in unidirectional airflow cleanrooms, clean zones and controlled zones. However, the method can also be used in non-unidirectional areas.

B.3.3 Procedures for airflow direction test and visualization

B.3.3.1 Tracer thread method

The test is carried out by observation of tufts, e.g. silk threads, single nylon fibres or thin film tapes. These are set on the tip of support sticks or mounted on the crossing points of thin wire grids in the airflow. They provide visual indication of the airflow direction and fluctuations due to turbulence. Effective lighting will aid observation and recording of the indicated airflow.

B.3.3.2 Tracer injection method

The test is carried out by observation or imaging of the behaviour of tracer particles, which can be illuminated by high-intensity light sources. The test provides information about the airflow direction and uniformity of velocity in a cleanroom, clean zone or controlled zone. The tracer particles can be generated from materials such as de-ionized (DI) water, sprayed or chemically generated alcohol/glycol, etc. The source should be carefully selected to avoid contamination of surfaces.

The desired size of droplets should be considered when selecting the droplet generation method. Droplets should be large enough to be detected with the available image processing techniques, but not so large that gravitational or other effects result in their motion diverging from that of the airflow being observed.

B.3.3.3 Airflow visualization method by image processing techniques

Processing particle image data derived from the method described in B.3.3.2 on video frames or films provides quantitative characteristics of airflow by way of two-dimensional air velocity vectors in the area. The processing technique requires a digital computer with suitable interfaces and the appropriate software. For greater spatial resolution, devices such as a laser light sources can be used.

B.3.3.4 Evaluation of airflow distribution by measurement of velocity distributions

The velocity distributions of airflow can be determined by setting air velocity measuring apparatus, such as thermal or ultrasonic anemometers, at several defined points in the cleanroom or clean zone under investigation. Processing of the measured data provides the information about the airflow distribution.

B.3.4 Apparatus used for airflow direction test and visualization

The apparatus used for the airflow direction test and visualization is different for each test method. The apparatus suitable for each test method is given in C.4, Table B.1 and B.2.

Table B.1 — Materials or particles used in tracer thread or injection methods

Item	Description
Material used in the tracer thread method	Silk thread, cloth, etc.
Particulate method used in the tracer injection method	DI water or other fluid mist of 0,5 µm to 50 µm in diameter. Bubbles of neutral density in the air at the measuring location. Organic or inorganic test fog.
Image recording devices for recording the visualized pictures or images of tracer particles	Various devices, such as photographic cameras, video cameras, including high-speed or strobe or synchronized functions and image recording devices, used in flow visualization procedures.

NOTE After flow visualization, it is generally necessary to re-clean the cleanroom or clean zone.

Table B.2 — Illumination light sources for airflow visualization

Item	Description
Various illumination light sources for contrasted observation or imaging of airflows	Tungsten lamp, fluorescent lamp, halogen lamp, mercury lamp, laser light sources (He-Ne, argon ion, YAG lasers, etc.) with or without stroboscope or devices synchronized to the recorders.
Image-processing technique for quantitative measurement by flow visualization	Laser light sheet method, consisting of high-power laser sources (argon or YAG laser), optics including cylindrical lens, and a controller, where two-dimensional airflows are visualized.

B.3.5 Test reports

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

a) type of tests, method of visualization and test conditions;

b) type designations of each measuring apparatus used and its calibration status;

c) visualization point locations;

d) images stored on photographs or any other recording media, or raw data for each measurement, in the case of the image processing technique or the measurement of velocity distributions, if specified;

e) a plan of the exact location of all apparatus should accompany the flow visualization report;

f) occupancy state(s).

B.4 Recovery test

B.4.1 General

This test is performed to determine the ability of the installation to reduce the concentration of airborne particles by dilution. Cleanliness recovery performance after a particle generation event is one of the most important abilities of the installation. This test is only recommended for non-unidirectional airflow systems as the recovery performance is based on the dilution and mixing of the air found in non-unidirectional airflow systems, and not unidirectional airflow systems, where contamination is removed by the unidirectional flow of air. The recovery performance of a non-unidirectional cleanroom is affected by air distribution characteristics such as ventilation effectiveness, thermal conditions, and obstructions. The recovery test can be performed using an LSAPC or an aerosol photometer. When an artificial aerosol is used, the risk of residue contamination of the cleanroom or clean zone should be considered.

B.4.2 Cleanliness recovery performance

Recovery performance is evaluated by using the 100:1 or 10:1 recovery time and/or the cleanliness recovery rate. The 100:1 or 10:1 recovery time is defined as the time required for decreasing the initial concentration by a factor of 100 times (or 10 times). The cleanliness recovery rate is defined as the rate of change of particle concentration by time. It is possible to estimate both of these from the same particle concentration decreasing curve. The measured concentration levels used should be taken from inside the time range where the decreasing of particle concentration is described by a single exponential, indicated by a straight line on a semi-log chart (concentrations on the ordinate by the logarithmic scale, and the time values on the abscissa by the linear scale). Moreover, the test concentration should not be so high that coincident loss occurs, or so low that counting uncertainty occurs.

The purpose of the recovery time test is to evaluate an actual time interval for the concentration to reach target cleanliness level after the particle concentration in the cleanroom or clean zone has temporarily become higher due to planned maintenance shutdown, or unplanned plant failure. The purpose of evaluation by recovery rate is to establish the local ability to recover the cleanliness after the particle concentration around the measuring point has temporarily become higher. The slope of decreasing curve on a semi-log chart indicates this local ability.

The 100:1 test is not recommended for ISO Classes 8 and 9.

NOTE The measurement of the recovery rate not only gives the recovery rate but the air change rate per unit of time at the location where the measurements were made. If the local air change rate at the location is compared to the overall air change rate in the cleanroom, the effectiveness of the ventilation system in providing clean air at the measuring location can be obtained.

B.4.3 Procedure for recovery test

B.4.3.1 Selection of measuring points

Place the LSAPC probe in the working plane at appropriate location(s) (which can include critical locations or suspected worst-case locations). The measuring points and number of measurements should be determined between the customer and supplier. It can be inappropriate to choose measuring locations that give recovery performances not representative of the cleanroom, such as under an air terminal without a diffuser.

B.4.3.2 Test method

Care should be taken to avoid high airborne concentrations of particles that can cause coincidence error and contamination of the LSAPC optics. Before testing, calculate the concentration required to carry out the recovery test. If the concentration exceeds the maximum concentration of the LSAPC, where particle coincidence will occur, use a dilution system. Testing procedure:

a) set up the particle counter in accordance with the manufacturer's instructions and the apparatus calibration certificate;

b) the particle size used in this test should be less than 1 μm. It is recommended that the size channel used by the LSAPC corresponds to that of the maximum number concentration of the aerosol;

c) the cleanroom area to be examined should be contaminated with an aerosol while the air-handling units are in operation;

d) raise the initial particle concentration to more than 10 or 100 times depending on the target cleanliness level (see Note 1);

e) commence measurements at not more than 1 min intervals and record time and concentration.

f) The results of the decay of the logarithm of the particle concentration should be plotted against time to ensure that the results used are where the decay is exponential, i.e. the decay line is straight, and not at the beginning where the decay has not been established, or at the end where the background count in the cleanroom reduces the decay rate.

NOTE 1 The target cleanliness level can be either the design cleanliness level, the level established by testing according to ISO 14644-1 at the at-rest condition, or an alternative agreed cleanliness level, assuming that the level is at a point on the decay graph where the decay is exponential.

NOTE 2 If necessary, an alternative, but less convenient method, can be to turn off the ventilation system, add the test particles, mix with a room fan if needed, and turn on the ventilation system.

B.4.3.3 Evaluation by 10:1 or 100:1 recovery time

Evaluation procedure:

a) note the time when the particle concentration reaches the 10× or 100× target concentration threshold (t_{10n} or t_{100n});

b) note the time when the particle concentration reaches the target cleanliness level, t_n;

c) the 10:1 recovery time is represented by $t_{0,1} = (t_n - t_{10n})$;

d) the 100:1 recovery time is represented by $t_{0,01} = (t_n - t_{100n})$.

B.4.3.4 Evaluation by recovery rate

Recovery performance can be determined from the slope of the particle concentration decreasing curve, as follows:

a) commence measurements and record time and concentration continuously. Sampling time should be as short as possible but sampling should be such that the count has statistical relevance. Time intervals between the samplings should be as short as possible;

b) plot the data of decreasing particle concentration on a semi-log chart (concentrations on the ordinate by the logarithmic scale, and the time values on the abscissa by the linear scale);

c) decide higher and lower concentration limits as to the decreasing curve measured is accepted as almost straight line;

d) cleanliness recovery rate is obtained from the slope of the line between the higher and lower concentrations. The cleanliness recovery rate between two measurements is calculated from Formula (B.6):

$$r = -2{,}3 \times \frac{1}{t1 - t0} \log\left(\frac{C_1}{C_0}\right) \tag{B.6}$$

where

C_0 is the higher concentration at t_0;

C_1 is the lower concentration at t_1.

r is the cleanliness recovery rate;

$t_1 - t_0$ is the time between measured concentration crosses C_0 and C_1;

NOTE The ventilation effectiveness of a critical location or locations in the cleanroom can be determined by comparing the recovery rate at the location or locations with the overall recovery rate of the cleanroom. When the air and the contamination in the cleanroom are perfectly mixed at the start of the recovery test for the cleanroom, the overall recovery rate of a cleanroom is the same as the air change rate of the cleanroom. Therefore, the ventilation effectiveness can be obtained by comparing the recovery rate at the location or locations with the air change rate of the cleanroom.

To obtain comparable values of the recovery test, it is necessary to consider the influence of the temperature difference between incoming air and the recovery performance test point, which causes changes to the airflow in the cleanroom. This temperature difference can vary between the at-rest and as-built conditions, due to changes in the heat gains in the cleanroom, and between the different requirements for seasonal warming or cooling. The temperature differential between the incoming air and recovery test point should be measured.

B.4.4 Apparatus for recovery test

The apparatus listed below can be used for a recovery test:

- aerosol generator and artificially generated aerosol, which have the same characteristics as those described in C.5;
- light-scattering airborne-particle counter (LSAPC), which has the efficiency described in C.5.1;
- dilution system, if necessary, as described by C.5.4;
- thermometer.

NOTE A recovery test can also be carried out using an aerosol photometer.

B.4.5 Test reports

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

a) type designations of each measuring apparatus used and its calibration status;

b) number and location of measuring points;

c) occupancy state(s);

d) result of measurement.

B.5 Temperature test

B.5.1 General

The purpose of this test is to verify the capability of the installation to maintain the air temperature level within the control limits and over the time period agreed between the customer and supplier for the particular area being tested. Refer to ISO 7726[28] and other related documents for details of suitable test methods.

B.5.2 Apparatus for temperature test

The temperature test should be performed using a sensor that has accuracy as defined in ISO 7726,[28] for example:

a) thermometers;

b) resistance temperature devices;

c) thermistors.

The apparatus should have a valid calibration certificate.

B.6 Humidity test

B.6.1 General

The purpose of this test is to verify the capability of the installation to maintain the air humidity level (expressed as relative humidity or dew point) within the control limits and over the time period agreed between the customer and the supplier for the area being tested. Refer to ISO 7726[28] and other related documents for details of suitable test methods.

B.6.2 Apparatus for humidity test

Humidity tests should be performed using a sensor that has accuracy appropriate to the measurement as stated in ISO 7726[28].

Typical sensors are:

a) dielectric thin film capacitor humidity sensor;

b) dew point sensor;

c) psychrometer.

B.7 Installed filter system leakage test

WARNING — The aerosol challenge can provide an unacceptable particulate or molecular contamination within some installations. Some test aerosols can create a safety hazard under certain circumstances. This document does not address any safety issues associated with these methods. It is the responsibility of the user to consult and apply appropriate safety practices, risk assessments and any regulatory limits prior to use of this document.

B.7.1 General

B.7.1.1 Methods

These tests are performed to confirm that installed filter systems with integral efficiency of 99,95 % or higher at most penetrating particle size (MPPS) are properly installed by verifying the absence of bypass leakage in the 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). Portions of the test methods given in B.7 have been adapted from IEST-RP-CC034.4[21].

These tests are not used to determine the efficiency of the filter medium. The leak test establishes the level of leakage, relevant to the cleanliness performance of the installation. 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. The test is applied to cleanrooms and clean zones in as-built or in at-rest occupational states, and undertaken when commissioning new cleanrooms and clean zones, or when existing installations require re-testing, or after the high-efficiency air filters have been replaced.

Two procedures for filter systems with ceiling, wall or apparatus mounted filters are described in B.7.2 and B.7.3. A procedure for duct mounted filters is described in B.7.4. The apparatus and methods are different, with the method described in B.7.2 measuring a mass concentration using an aerosol photometer and the method described in B.7.3 measuring numbers of particles using a LSAPC.

B.7.1.2 Aerosol photometer method

The aerosol photometer method (B.7.2) may be used for testing:

a) cleanrooms and clean zones with all types of air-handling systems;

b) installations where outgassing of oil-based volatile test aerosol deposited on the filters and ducts is not considered to be detrimental to products and/or processes and/or personnel within the cleanroom or clean zone.

NOTE The aerosol photometer method can require a higher upstream aerosol concentration, when compared to the LSAPC method.

B.7.1.3 Light-scattering airborne-particle counter (LSAPC) method

The LSAPC method (B.7.3) may be used for testing:

a) cleanrooms and clean zones with all types of air-handling systems;

b) installations where outgassing of oil-based volatile aerosol deposited on filters and ducts cannot be tolerated or where the use of solid aerosol is recommended.

NOTE 1 This method requires a series of calculations to set up the method and can also require the use of a diluter (see C.5.4). The calculations can be manual, through independent computers, instrument linked computers, or within automated adapted LSAPC instruments.

NOTE 2 This method can also be used with oil-based aerosol where outgassing can be tolerated.

B.7.2 Procedure for installed filter system leakage scan test with an aerosol photometer

B.7.2.1 General

Preparatory steps are contained in B.7.2.2, B.7.2.3, B.7.2.5 and B.7.2.6, acceptance criteria in B.7.2.4, the test procedure itself in B.7.2.7, and repair actions are to be found in B.7.6[17][18][21].

B.7.2.2 Determination of probe size

It is desirable to choose a probe which has a rectangular inlet in sizes of D_p = 1 cm and W_p = 8 cm or a circular probe of diameter D_p = 3,6 cm. D_p is the probe dimension parallel to the scan direction, expressed in centimetres; W_p is the probe dimension perpendicular to the scan direction, expressed in centimetres.

B.7.2.3 Determination of scan rate

The probe traverse scan rate, S_r, should be approximately 5 cm/s[21].

B.7.2.4 Acceptance criteria

While scanning, any indication of a leak equal or greater than the limit which characterizes a designated leak should be cause for holding the probe at the leak location. The location of the leak should be identified by the position of the probe that sustains the maximum reading on the aerosol photometer.

A leak detected in excess of 0,01 % of the upstream mass concentration is deemed to exceed the maximum allowable penetration. However, for filter systems of an integral efficiency at MPPS ≧ 99,95 % and less than 99,995 %, the acceptance criterion is 0,1 %.

If filter systems of an integral efficiency lower than 99,95 % at MPPS are to be tested, a different acceptance criterion are necessary, based on agreement between customer and supplier.

For actions to be taken to eliminate detected leaks, see B.7.6.

B.7.2.5 Choice of upstream aerosol challenge

An artificially generated aerosol by Laskin nozzle, thermal generator or similar should be introduced into the upstream airflow to achieve the required homogeneous challenge concentration. The mass median particle diameter for this production method is typically between 0,3 µm to 0,7 µm with a geometric standard deviation of up to 1,7.

NOTE A guide to aerosol source substances is given in C.8.4.

B.7.2.6 Concentration of upstream aerosol challenge and its verification

The concentration of the aerosol challenge upstream of the filter should be between 1 mg/m^3 and 100 mg/m^3.

NOTE Not all photometers are capable of using 1 mg/m^3 as the upstream challenge.

Appropriate measurements should be taken for the verification of the homogenous mixing of the added aerosol to the supply airflow. The first time a system is tested, it should be determined that sufficient aerosol mixing is taking place. For such validation, all injection and sampling points should be defined and recorded.

The upstream aerosol concentration measurements taken immediately upstream of the filters should not vary more than ±15 % in time about the average measured value. Concentrations lower than the average reduce the sensitivity of the test to small leaks, while higher concentrations increase the sensitivity to small leaks. Further details as to how to conduct the air-aerosol mixing test should be agreed between customer and supplier.

B.7.2.7 Procedure for installed filter system leakage scan test

Prior to performing this procedure, the airflow velocity test (B.2) should be carried out. Where installations are operated at different airflow velocities, the highest level should be selected for the filter system leakage scan test. The test is performed by introducing the specific challenge aerosol upstream of the filter(s) and searching for leaks by scanning the downstream side of the filter(s) and the grid or mounting frame system with the photometer's probe as follows:

a) measure the aerosol concentration upstream of the filters according to B.7.2.6. This aerosol concentration should be used as the upstream 100 % reference for the photometer. Downstream measurements is then displayed as percentage penetration of upstream concentration;

b) the probe should then be traversed at a scan rate not exceeding 5 cm/s using overlapping strokes (1 cm recommended). The probe should be held in a distance of 3 cm or less from the downstream filter face or the frame structure;

c) scanning should be performed over the entire downstream face of each filter, the perimeter of each filter, the seal between the filter frame and the grid structure, including its joints;

d) measurements of the aerosol upstream of the filters should be repeated at reasonable time intervals between and after scanning for leaks, to confirm the stability of the challenge aerosol concentration (see B.7.2.6).

B.7.3 Procedure for installed filter system leakage scan test with a LSAPC

B.7.3.1 General

Preparatory steps are contained in B.7.3.2 to B.7.3.7, test procedure in B.7.3.8 and B.7.3.9. acceptance criteria in B.7.3.4 and repair actions in B.7.6. An example of an application with evaluation is contained in B.7.3.10.

This method has a two-stage approach:

— Stage 1: the clean side of the filter should be scanned for a potential leak. During scanning with a LSAPC, detection of more than an acceptable count for given test conditions, N_a, in sample acquisition time, T_s, indicates the potential presence of a leak. In this case, the second stage should be performed. If there are no indications of potential leaks, further investigations are not necessary. The determination of N_a is described in B.7.3.5 and T_s is described in B.7.3.8.2. The procedure for stage 1 scan test is described in B.7.3.8.

— Stage 2: the probe should be returned to the place of maximum particle count under each potential leak and a stationary re-measurement should be performed. During the stationary re-measurement with the LSAPC, detection of more than acceptable count for given test conditions, N_{ar}, in sustained residence time, T_r, indicates the presence of a leak. The determinations of N_{ar} and T_r are described in B.7.3.9.2. The procedure for stage 2 stationary re-measuring is described in B.7.3.9.

B.7.3.2 Determination of probe size

The area of the probe size should ensure that the air velocity into the probe is the same as at the filter face, within a variation of ±20 %. The area of the intake probe can be calculated by means of Formula (B.7):

$$D_p \times W_\mathrm{p} = Q_{va}/U \qquad \text{(B.7)}$$

where

D_p is the probe dimension parallel to the scan direction in cm;

Q_{va} is the sampling rate of the LASPC in cm^3/s;

U is the filter face velocity in cm/s.

W_p is the probe dimension perpendicular to the scan direction, in cm;

It is desirable to choose a probe which has a rectangular inlet in sizes of D_p = 1 cm and W_p = 8 cm or a circular probe of diameter $\mathrm{D_o}$ = 3,6 cm. Recommended probe dimensions are based on a sample flow rate, Q_{vs}, of 0,000 472 m^3/s (= 472 cm^3/s, 28,3 l/min or 1 CFM).

If filter face velocity is unusually high (>1 m/s), a smaller dimension for the probe, D_p, can be calculated by use of Formula (B.7).

For a circular probe, Formula (B.8) can be used to determine the value of D_p.

$$D_p = 2 \times \sqrt{D_0 \times W_s - W_s{}^2} \qquad \text{(B.8)}$$

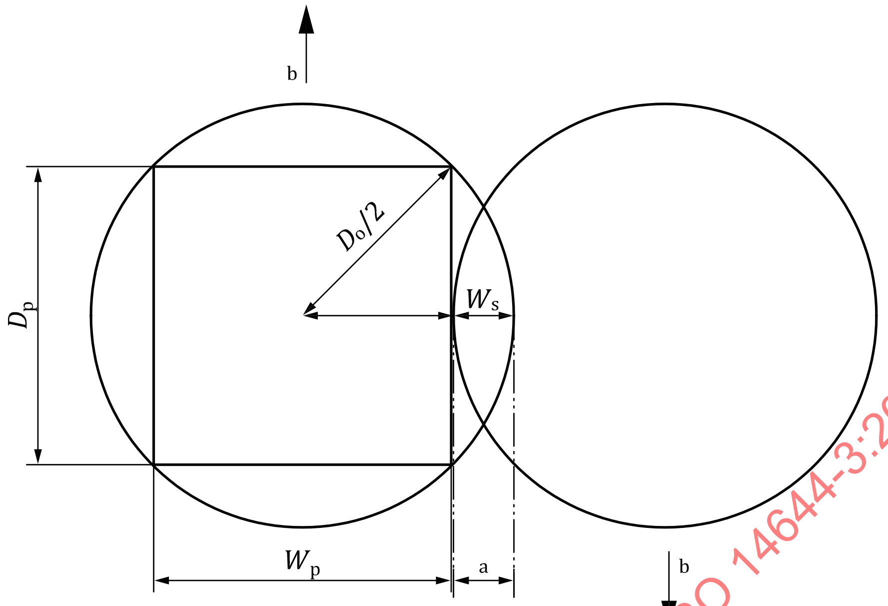
where

D_p is the nominal probe dimension parallel to the scan direction, in cm;

D_0 is the actual probe dimension (diameter), in cm;

W_s is the probe overlap dimension perpendicular to the scan direction, in cm.

For a circular probe of a 3,6 cm, diameter, D_p, is 2,54 cm.



Key

a Overlap.

b Scan direction.

Figure B.1 — Circular probe dimensions diagram

NOTE In order to scan the target surface area most efficiently, it is necessary to select W_s as D_p becomes equal to W_p. In case of circular probe with a diameter of 3,6 cm, the most efficient D_p is 2,54 cm.

B.7.3.3 Determination of scan rate

For a rectangular probe inlet size of D_p = 1 cm and W_p = 8 cm, the probe scan rate, S_r, is 5 cm/s or less.

For a circular probe inlet diameter of 3,6 cm, the probe scan rate, S_r, is 12 cm/s or less.

Where the upstream aerosol concentrations cannot be achieved, it is necessary to change the scan rate. The scan rate, S_r, in cm/s can be determined by assuming the sampling rate of the LSAPC is 0,000 472 m^3/s and use Formula (B.9).

$$S_r = C_c \times P_l \times 0{,}000\,472 \times \frac{D_p}{N_p} \tag{B.9}$$

where

C_c is the challenge aerosol concentration upstream of the filter in particles/m^3;

N_p is the expected median of particle counts that characterize a designated leak in particles;

P_l is the maximum permitted penetration of the filter installation to be tested at 0,3 µm.

B.7.3.4 Particle size to be counted and acceptance criteria

The particle size to be counted should be equal to or greater than 0,3 µm.

While scanning, any indication of a leak should be cause for holding the probe at the leak location. The location of the leak should be identified by the position of the probe.

A leak detected in excess of 0,01 % of the upstream number concentration is deemed to exceed the maximum allowable penetration. However, for filter systems of an integral efficiency at MPPS ≧ 99,95 % and less than 99,995 %, the acceptance criterion is 0,1 %.

If filter systems of an integral efficiency lower than 99,95 % at MPPS are to be tested, a different acceptance criterion is necessary, based on agreement between customer and supplier.

B.7.3.5 Expected number of particle counts

The acceptable number of particle counts during the scanning (Stage 1) is N_a and it is desirable to select a N_a value of 0 or 1.

The lower confidence limit will determine N_a. It can be calculated with Formula (B.10).

$$N_a = N_p - 2\sqrt{N_p} \tag{B.10}$$

where N_p is the expected median of particle counts that characterize a designated leak of particles.

It is the value N_p that is carried forward in Formula (B.9), and Formula (B.11) can be used to calculate N_p:

$$N_p = (N_a + 2) + 2\sqrt{1 + N_a} \tag{B.11}$$

When $N_a = 0$, N_p is 4, and when $N_a = 1$, N_p is 5,83.

NOTE Higher values of N_a and N_p can be selected if there are concerns with false positives being caused by a "bleed through" of particles in undamaged filter media.

B.7.3.6 Choice of upstream aerosol challenge

An artificially generated polydisperse aerosol should be introduced into the upstream airflow to achieve the required homogeneous challenge concentration. The count median particle diameter for this production method is typically between 0,1 µm to 0,5 µm with a geometric standard deviation of up to 1,7. The median particle diameter for this production method is typically between 0,3 µm and 0,7 µm with a geometric standard deviation of up to 1,7.

Alternatively, microspheres with an appropriate diameter can be used and an aerosol challenge.

Where an artificial aerosol cannot be introduced, atmospheric aerosol should be used as the upstream aerosol challenge.

NOTE A guide to aerosol source substances is given in C.8.4.

B.7.3.7 Concentration of upstream aerosol challenge and its verification

The concentration of the aerosol challenge upstream of the filter should be sufficiently high to achieve acceptable practical scan rates according to B.7.3.3. The concentration of aerosol challenge upstream of the filter is determined with Formula (B.12):

$$C_c \geq N_p \times S_\mathrm{r} / (Q_{V\mathrm{s}} \times D_\mathrm{p} \times P_L) \tag{B.12}$$

where

C_c is the challenge aerosol concentration upstream of the filter, in particles/m^3;

D_p is the probe dimension parallel to the scan direction, in cm;

P_l is the maximum permitted penetration of the filter installation to be tested at 0,3 µm.

Q_{Vs} is the actual sample flow rate of the measuring apparatus, in m^3/s;

S_r is the probe traverse scan rate, in cm/s;

Based on the recommend probe size and scan rate as stated in B.7.3.2 and B.7.3.3, the concentration of aerosol challenge upstream of the filter can be selected by using Formula (B.12).

In most cases, generated aerosol should be added to the upstream aerosol challenge to reach the necessary high challenge concentration. To verify such high concentrations, a dilution system can be required to avoid exceeding the concentration tolerance of the LSAPC (coincidence error).

Challenge aerosol concentrations can be adjusted by changing the probe scan rate by use of Formula (B.9).

Appropriate measurements should be taken for verification of the homogenous mixing of the added aerosol to the supply airflow. The first time a system is tested, it should be determined that sufficient aerosol mixing is taking place. For such validation, all injection and sampling points should be defined and recorded.

The upstream aerosol concentration measurements taken immediately upstream of the filters should not vary more than ±15 % in time from the average measured value. Concentrations lower than the average will reduce the sensitivity of the test to small leaks, while higher concentrations increase the sensitivity to small leaks. Further details as to how to conduct the air-aerosol mixing test should be agreed between customer and supplier.

When upstream aerosol concentrations vary over the time, these measurements should be continued during scanning for leaks in order to gain data for calculations with sequential downstream counts.

B.7.3.8 Procedure for installed filter system leakage test, stage 1 scan test

B.7.3.8.1 General

Prior to performing this procedure, the airflow velocity test (see B.2) should be carried out. Where installations are operated at different airflow velocities, the highest level should be selected for the filter system leakage scan test. The test is performed by introducing the specific challenge aerosol upstream of the filter(s) and searching for leaks by scanning the downstream side of the filter(s) and the grid or mounting frame system with the LSAPC probe as follows:

a) measurements of the aerosol upstream of the filters according to B.7.3.7 should be taken first to verify the aerosol concentration;

b) the probe should then be traversed at a scan rate not exceeding the value for S_r stated in B.7.3.3, using slightly overlapping strokes. The probe should be held in a distance of approximately 3 cm from the downstream filter face or the frame structure;

c) scanning should be performed over the entire downstream face of each filter, the perimeter of each filter, the seal between the filter frame and the grid structure, including its joints;

d) measurements of the aerosol upstream of the filters should be repeated at reasonable time intervals between and after scanning for leaks, to confirm the stability of the challenge aerosol concentration (see B.7.3.7).

B.7.3.8.2 Measuring parameters for two scanning types

Generally, LSAPCs are designed to count particles in a specific volume of sampled air. Many LSAPCs are not capable of outputting the data of particle counts during very short periods in continuous measurement.

Thus, the conditions for $N_a = 0$ or $N_a = 1$ (N_a is acceptable count for given test conditions) should be chosen in the installed filter system leakage scan test with the LSAPC.

Choosing this condition, leakage is verified with each count during the test, or with the period between counts.

If the apparatus is equipped to emit a sound for each count, leakage can be verified using this sound.

If the apparatus can output the counts during very short periods in continuous measurement, any N_a is applicable. Absence of a leak is verified if the observed count is equal to or less than N_a at the time (D_p / S_r).

For reasonable test conditions, the following two scanning types can be selected:

a) Scanning type (a): Choosing $N_a = 0$ for 0,3 µm particles;

  - suitable when the frequency of stationary re-measuring is predicted to be very small;
  - type (a) test requires lower concentration for upstream than type (b);
  - absence of a leak is verified if the count is 0; the scanning test can be continued.

b) Scanning type (b): Choosing $N_a = 1$ for 0,3 µm particles;

  - suitable when predicted that stationary re-measuring may be necessary;
  - type (b) test requires higher concentration for upstream than type (a), however the influence of LSAPC count error is reduced;
  - if the observed count is 0 or 1, absence of a leak is verified. The scanning test can be continued.

B.7.3.9 Procedure for stationary re-measuring

B.7.3.9.1 General

The observation of a particle count larger than N_a indicates the potential presence of a leak, and the location should be checked by stationary re-measuring.

B.7.3.9.2 Detection of leakage by stationary re-measuring

a) Observed counts smaller than N_{ar} [particles]: the observed counts for T_r, equal to or smaller than N_{ar} confirm an absence of leaks.

b) Observed counts larger than N_{ar} [particles]: if the observed count exceeds N_{ar}, stationary re-measuring may be considered. If the observed count still exceeds N_{ar}, the filter should be considered to have a leak.

B.7.3.9.3 Determination of measuring parameters for stationary re-measuring

Recommended sustained residence time, T_r, is 10s.

The number of particle counts that characterizes the designated leak, N_pr, and acceptable count at stationary re-measuring, N_{ar}, are calculated with Formulae (B.13) and (B.14):

$$N_{pr} = C_c \times P_l \times Q_{VS} \times T_\mathrm{r} \tag{B.13}$$

$$N_{ar} = N_{pr} - 2\sqrt{N_{pr}} \tag{B.14}$$

where

C_c	is the challenge aerosol concentration upstream of the filter in particles/m^3;
D_p	is the probe dimension parallel to the scan direction in cm.
N_{ar}	is acceptable count at stationary re-measuring;
N_{pr}	is the number of particle counts which characterize the designated leak;
P_l	is the maximum permitted penetration of the filter installation to be tested at 0,3 µm;
Q_{VS}	is the actual sample flow rate of the measuring apparatus in m^3/s;
T_r	is the recommended sustained residence time(s);

B.7.3.10 Example of an application with evaluation

Examples of measuring parameters are shown in Table B.3. These tables give example parameters for D_p = 1 cm and W_p = 8 cm with a scan rate S_r = 5 cm/s, and a circular probe with diameter 3,6 cm and a scan rate S_r = 12 cm/s.

Table B.3 — Example of an application with evaluation

Measuring parameters		**Rectangular probe (1 cm × 8 cm)**		**Circular probe (diameter 3,6 cm)**	
	Scanning type	**type (a)**	**type (b)**	**type (a)**	**type (b)**
P_l	Maximum allowable penetration of the filter system to be tested	0,000 1(0,01%)		0,000 1(0,01%)	
D_p	Nominal probe dimension parallel to the scan direction [cm]	1		2,54	
S_r	Probe traverse scan rate [cm/s]	5		12	
Q_{vs}	Sample flow rate of the measuring apparatus [m^3/s]	0,000 472		0,000 472	
N_p	Expected number of particle counts that characterizes the designated leak corresponding to N_a [counts] – Stage 1	4,0	5,83	4,0	5,83
N_a	Acceptable count during T_s at scan test [counts] – Stage 1	0	1	0	1
C_c	Challenge aerosol concentration upstream of the filter [particles/m^3]	423 728 814	617 584 746	400 373 682	583 544 642
N_{pr}	Expected number of particle counts during T_r = 10 s in the sustained residence time that characterizes the designated leak corresponding to N_{ar} [counts] – Stage 2	200,00	291,50	188,98	275,43
N_ar	Acceptable count during T_r = 10 s in the sustained residence time [counts] – Stage 2 (rounded)	171,72 (171)	257,35 (257)	161,48 (161)	242,24 (242)

B.7.4 Procedure for overall leak test of filters mounted in ducts or air-handling units (AHUs)

This procedure may be used for evaluating the overall leakage of duct-mounted filters. This procedure may also be used to determine overall leakage of multistage filter arrays without individual stage tests. It is important to be aware that this procedure is significantly less sensitive at finding leaks than the method described in B.7.2 and B.7.3. The overall leakage test result is affected by the total airflow volume in the system, as the airflow volume increases more dilution of the leak occurs. Therefore, this test method should be used where duct-mounted filter installations serve less critical cleanroom areas and where scan testing of those same filter installations is not practical. If critical, the scan method should be adopted.

NOTE 1 This test is not designed to cover exhaust HEPA filter systems.

The test is performed by introducing the challenge aerosol upstream of the filters installed remotely to the cleanroom or clean zone. The upstream particle concentration is first measured. The particle concentration of the filtered air is then measured, and compared to the upstream concentration to determine the total leakage or penetration of the filter installation[19].

The airflow velocity test (see B.2) for initial qualification should be done prior to performing this test. Measurements of the upstream aerosol concentration according to B.7.2.6 (aerosol photometer method) or B.7.3.7 (LSAPC method) should be taken first to verify the aerosol concentration and homogeneity.

Measurement of downstream aerosol concentration should be carried out at locations where homogeneous mixing has occurred. If homogeneous mixing does not occur, a series of measurements should be taken at equally spaced locations in an agreed plane, between 30 cm and 100 cm downstream of the filter. This is a grid sampling method and the location and number of measurements should be agreed between the customer and the supplier.

Measurements of the total aerosol challenge or particle concentrations upstream of the filters should be repeated at reasonable time intervals to confirm stability of the challenge aerosol source (see B.7.2.6 and B.7.3.7).

Using a photometer, from the measured total challenge or concentration, the local penetration is measured as percentage penetration for each downstream location measurement. Using a LSAPC, from the measured particle challenge concentration, the local percentage penetrations should be calculated for each downstream location measurement for the particle size used. Each downstream percentage concentration should be lower than the percentage concentration specified, or as agreed between customer and supplier.

Repairs or rectification of leaks may be made according to B.7.6 or by procedures agreed between the customer and the supplier.

NOTE 2 For applications, where ducted filters are required to be leak tested by scanning, the methods are described in B.7.2 and B.7.3.

B.7.5 Apparatus and materials for installed filter system leakage tests

B.7.5.1 Aerosol photometer (see C.8.1), limited to use in instances where the background counts or concentrations are less than 10 % of that which characterizes a designated leak

B.7.5.2 Light-scattering airborne-particle counter (LSAPC) (see C.8.2), limited to use in instances where the background counts or concentrations are less than 10 % of that which characterizes a designated leak.

B.7.5.3 Suitable pneumatic or thermal aerosol generator(s) to provide appropriate challenge aerosol concentration in the appropriate size range (see C.8.3).

B.7.5.4 Aerosol dilution system (see C.5.4).

B.7.5.5 Aerosol source substances (see C.8.4).

Apparatus specified in B.7.5.1 to B.7.5.3 should have a valid calibration certificate.

B.7.6 Repairs and repair procedures

Leakage repair should only be acceptable by agreement between the customer and the supplier. The method of repair should take into account any instructions from the apparatus manufacturer, or the customer.

In selecting materials for repair, outgassing and molecular deposition on products and processes should be considered.

Detected leakage in filters, the sealant or the grid structure should be repaired.

Repairs to filter or the grid support structure may be made using procedures agreed between the customer and supplier.

After the repair has been completed and a suitable cure time has been allowed, the leak site should be rescanned for leaks using the defined method.

B.7.7 Test reports

By agreement between the customer and supplier, the following information and data should be recorded as described in Clause 5:

a) test method: aerosol photometer or light-scattering airborne-particle counter (LSAPC);

b) type designations of each measuring apparatus used and its calibration status;

c) specification of the filter;

d) any special condition or departures or both from this test method and any special procedures agreed between the customer and the supplier;

e) measured upstream aerosol concentrations with their sample point locations and the corresponding time of measurement;

f) sample flow rate; and for LSAPC measurements, the particle size range;

g) calculated average upstream aerosol concentration and its distribution;

h) calculated acceptance criteria applied for the downstream measurements;

i) result of the downstream measurement for each clearly identified filter, area section or measuring location;

j) final result of the test for each defined location;

k) if there is no leakage, then test passed. Otherwise if there is leakage then report leak location, repair action and result of re-testing the location.

B.8 Containment leak test

B.8.1 General

This test is performed to determine if there is intrusion of contaminated air into the clean zones from surrounding non-controlled areas and to check pressurized ceiling systems for leaks.

B.8.2 Procedures for containment leak test

B.8.2.1 Light-scattering airborne-particle counter (LSAPC) method

Measure the particle concentration outside the cleanroom enclosure immediately adjacent to the surface or doorway to be evaluated. This concentration should be greater than the cleanroom concentration by a factor of 10^3, and equal to at least ($3{,}5 \times 10^6$) particles/m^3 at the particle size to be measured. If the concentration is less, generate an aerosol to increase the concentration.

To check for leakage through construction joints, cracks or service conduits, scan inside the enclosure at a distance of not more than 5 cm from the joint, seal or mating surfaces to be tested at a scan rate of approximately 5 cm/s.

To check for intrusion at open doorways, flow visualization methods are recommended.

Record and report all readings greater than 10^{-2} times the measured external aerosol particle concentration at the appropriate particle size.

NOTE The number and location of test points for this measurement are as agreed between customer and supplier.

B.8.2.2 Aerosol photometer method

Produce an aerosol outside the cleanroom or device in accordance with B.7.2.2 in concentration high enough to cause the aerosol photometer to exceed 0,1 %.

A reading in excess of 0,01 % indicates a leak.

To check for leakage through the construction joints, cracks or seams scan inside the enclosure at distance of not more than 5 cm from the joint, or seal surface to be tested, at a scan rate of approximately 5 cm/s.

To check for intrusion at open doorways, measure the concentration inside the enclosure at a distance of 0,3 m to 1 m from the open door.

Record and report all readings in excess of 0,01 % of the photometer scale.

B.8.3 Apparatus for containment leak test

B.8.3.1 Artificially generated aerosol source, as described in B.7.5, with a valid calibration certificate;

B.8.3.2 Light-scattering airborne-particle counter (LSAPC), as specified in C.8.2 (or **photometer**, as specified in C.8.1) with a valid calibration certificate and a lower particle size discrimination capability of 0,5 µm or smaller.

B.8.4 Test reports

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

a) type designations of each measuring apparatus used and its calibration status;

b) data collection technique;

c) measuring point locations;

d) occupancy state(s);

e) result of measurement.

B.9 Electrostatic and ion generator tests

B.9.1 General

This test consists of two parts. One is the electrostatic test and the other is the ion generator (ionizer) test. The purpose of the electrostatic test is to evaluate the level of electrostatic charge voltage on work and product surfaces, and the dissipation rate of electrostatic voltage of the floor, workbench top or other cleanroom or clean zone component. The static-dissipative property is evaluated by measuring surface resistance and leakage resistance on the surfaces. The ion generator test is performed to evaluate the performance of ion generators by measuring the discharge time of initially charged monitors, and by determining the offset voltage of isolated monitoring plates. The results of each measurement indicate the efficiency of eliminating (or neutralizing) static charges and the imbalance between the amount of generated positive and negative ions.

B.9.2 Procedures for electrostatic and ion generator tests

B.9.2.1 Procedure for electrostatic test

B.9.2.1.1 Measurement of surface voltage level

The presence of positive or negative electrostatic charges on work and product surfaces is measured using an electrostatic voltmeter or fieldmeter.

Adjust output of the electrostatic voltmeter or fieldmeter to zero by presenting the probe to face a grounded metal plate. The probe should be held such that the sensing aperture is parallel to the plate at a distance according to the manufacturer's instructions. The metal plate utilized for the zero adjustment should be of sufficient surface area for the required probe aperture size and proper probe-to-surface spacing.

To measure the surface voltage, place and hold the probe near the object surface whose charge is to be measured. The probe should be held in the same manner as for the zero adjustment. For a valid measurement, the surface area of an object should be sufficiently large, compared with the probe aperture size and probe-to-surface spacing.

Record the readout of the electrostatic voltmeter.

The measuring point or object selected for measurement should be determined by agreement between the customer and supplier.

B.9.2.1.2 Measurement of the static-dissipative property

The static-dissipative property is evaluated by measuring surface resistance (resistance between different positions on the surface) and the leakage resistance (resistance between the surface and ground). These values are measured using a high-resistance meter.

Surface or leakage resistance is measured using electrodes that have appropriate weight and dimensions. These electrodes should be set at the correct distance from the surface during the measurement of surface resistance.

Specific details of the test conditions should be agreed between customer and supplier.

B.9.2.2 Procedure for ion generator test

B.9.2.2.1 General

The purpose of this test is to evaluate performance of bipolar ion generators. The test consists of measurements of both discharge time and offset voltage. The measurement of discharge time is performed to evaluate the efficiency of eliminating static charges using ion generators. Measurement of offset voltage is performed to evaluate imbalance of positive and negative ions in the ionized airflow from ion generators. An imbalance of ions can result in undesirable residual voltage.

These measurements are performed using conductive monitoring plates, an electrostatic voltmeter, and a timer and power source. (Sometimes apparatus consisting of those parts is known as a charged plate monitor.)

B.9.2.2.2 Measurement of discharge time

This measurement is performed using monitoring plates that are (isolated conductive plates) of known capacitance (e.g. 20 pF). Initially the monitoring plate is charged to a known positive or negative voltage from a power source.

The change of static charge on the plate is measured while exposing the plate to the airflow that is ionized by the bipolar ion generators being evaluated. The change in plate voltage over time should be measured using an electrostatic voltmeter and a timer.

Discharge time is defined as the time that is necessary for the static voltage on the plate to be reduced to 10 % of the initial voltage condition.

Discharge time should be measured for both negative and positive charged plates.

Test point locations and results for acceptance criteria should be agreed between customer and supplier.

B.9.2.2.3 Measurement of offset voltage

Offset voltage is measured using a charged plate monitor mounted on an isolator. The charge on the isolated plate is monitored by an electrostatic voltmeter.

Initially, the plate should be grounded to remove any residual charge, and it should be confirmed that voltage on the plate is zero.

The offset voltage is measured by exposing the plate to the ionized airflow until the voltmeter readout becomes stable.

The acceptable offset voltage of an ion generator depends upon the electrostatic charge sensitivity of objects in the work area. The acceptable offset voltage should be determined by agreement between customer and supplier.

B.9.3 Apparatus for electrostatic and ion generator tests

B.9.3.1 Electrostatic voltmeter or electrostatic field meter, for measurement of the surface electrostatic voltage level for the electrostatic test;

B.9.3.2 High resistance ohm meter, for measurement of the static-dissipative property for the electrostatic test;

B.9.3.3 electrostatic voltmeter, or electrostatic field meter and conductive monitoring plate, or charged plate monitor for the ion generator test.

This apparatus is described in C.10. The apparatus should have a valid calibration certificate.

B.9.4 Test reports

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

a) type of tests and measurements, and measuring conditions;

b) type designations of each measuring apparatus used and its calibration status;

c) temperature, humidity and other environmental data if relevant;

d) measuring point locations;

e) occupancy state(s);

f) result of measurement;

g) other data relevant for measurement.

B.10 Particle deposition test

B.10.1 General

This test describes procedures and apparatus for measuring the particle deposition of particles that deposit from the air onto product or other critical work surface in a cleanroom or clean zone. The number of particles that deposit onto a given test surface area such as a witness plate, in a given time, are sized and counted using optical microscopes, electron microscopes, surface scanning apparatus, or real-time particle deposition rate detection device to obtain the particle deposition rate data. Particle deposition rate data should be reported in terms of mass, particle area or number of particles per unit surface area per unit of time.

B.10.2 Procedure for particle deposition test

B.10.2.1 Collection of particles on witness plates

The witness plate, which should be at the same electrical potential as the test surface, is placed in the same plane, and adjacent to the at-risk surface during the operational state. The at-risk surface is at the location of interest. The following procedures and methods should be followed when manipulating and collecting particles on witness plates or another test surface:

a) verify that all cleanroom ventilation systems are functioning correctly, in accordance with operational requirements;

b) identify each witness plate and clean to reduce the surface particle concentration to the lowest possible level. Determine the background concentration of particles on each witness plate before exposure;

c) maintain 10 % of the witness plates as controls. These should be handled in exactly the same manner as the test witness plates;

d) transport all witness plates to the test locations in such a manner as to prevent particle contamination from the air or by surface contact;

e) expose the test witness plate adjacent to an at-risk surface in the cleanroom, such as where the product is exposed to airborne contamination;

f) determine the time intervals for exposure of the test witness plates based upon the cleanroom air cleanliness and the particle counting apparatus. The exposure time should be from approximately one hour to the length of time necessary to obtain sufficient particle deposition to provide statistically valid data;

g) expose the witness plates during the operational state; it may be necessary to expose them during several manufacturing sessions to ensure that the plates are not used in unoccupied clean conditions where no product is exposed;

h) cover and collect the exposed witness plates after exposure and store in closed containers to protect from further contamination.

B.10.2.2 Counting and sizing collected particles

Counting and sizing of particles collected on test surfaces should be carried out to obtain reproducible data that can be used to determine the cleanliness of the location being tested.

When using a witness plate, the number of particles and their sizes can be determined by one of the following means:

a) optical light microscope with a calibrated linear or circular graticulate;

b) electron microscope with a calibrated grating with known line spacing;

c) surface scanner using size calibration information supplied by the manufacturer.

When using a witness plate, the PDR can be calculated as follows:

a) count and size the particles on the measurement area of the witness plates, including the control plates and categorize them in appropriate particle size ranges, based on the cumulative particle diameters;

b) subtract the values of the initial cleanliness of the witness plate from each test result;

c) calculate the net concentration in a given unit of measurement of surface area, and calculate the number that will deposit in a given time. When appropriate measurement units are used, this calculation yields a PDR in terms of the number of particles deposited per square metre per second.

Where multiple test results are obtained, record the mean PDR value at each location and, if appropriate, its standard deviation.

B.10.3 Apparatus for particle deposition test

Various apparatus may be used for counting and sizing particles that have settled onto a test surface. These fall into the following categories:

a) light microscopes (particles larger than or equal to 2 µm);

b) electron microscopes (particles larger than or equal to 0,02 µm);

c) wafer surface scanner (particles larger than or equal to 0,01 µm);

d) PDR detection device (particles larger or equal to 5 µm);

e) real-time PDR measurement device (particles larger than 15 µm).

When choosing the counting and sizing apparatus, consideration should be given to the suitability to detect particles in the relevant size range. Other factors to be considered include the time required for sample collection and analysis. The apparatus used should have a valid calibration certificate.

B.10.4 Determination of sampling time and surface area

The lower the PDR, the larger the required exposed surface area, A, and exposure time, T. The product of $A \times T$ should be large enough to allow accurate determination of the PDR. A value of 20 is suggested for use with the largest particle of interest [see Formula (B.15)]:

$$A \times T \geq 20 \tag{B.15}$$

where

A is the area of exposed surface;

T is exposure time.

B.10.5 Test reports

By agreement between customer and supplier, the following information and data should be recorded:

a) type of tests and measurements, measuring conditions, and occupancy state;

b) type designations of each measuring apparatus used and its calibration status;

c) measuring point locations;

d) result of measurement.

B.11 Segregation test

B.11.1 General

This test describes the procedures and apparatus required for assessment of the protective effect of a specific segregating airflow. Testing can be either across a doorway or across the perimeter of an area with a higher classification or a specific purpose different than the surrounding area. The test is performed by generating an airborne aerosol in the lesser classified area, measuring this as the reference concentration and counting the particle concentration just across the perimeter in the protected area. The test can be performed at various selected locations along the perimeter under assessment.

This test should be preceded by a classification of air by particles test in the surroundings as well as the protected area to determine the baseline particle concentration level. The challenging particle concentration should be of sufficient level to be able to assess the protection factor.

NOTE Airflow direction test and visualization can be performed to identify the perimeter of the protected area.

B.11.2 Procedure

B.11.2.1 Generation of reference concentration

To challenge the protective airflow in the surroundings, a sufficient number of particles should be generated. Recommended test aerosol particles are described in C.5.3. The mean particle size should be 0.5 µm and greater unless an alternative size is agreed between customer and supplier.

In order to be sufficient, the following should be considered:

a) verify that all cleanroom systems are functioning correctly, in accordance with an agreed occupancy state;

b) to establish the challenging concentration, the protective effect to be verified should be used to calculate the number of challenging particles based on the anticipated particle concentration within the protected zone. This anticipated concentration should at least be 10 times the baseline count in the point to be verified.

B.11.2.2 Equipment geometry

Test equipment geometry should be determined. The probe(s) in the protected area should not be more than 0,1 m from the determined air barrier. The challenge concentration probe in the lesser classified area should not be more than 1 m from the determined air barrier (between aerosol generator and air barrier). The aerosol generator should be positioned approximately 1 m to 1,5 m from the challenge concentration probe.

NOTE The number of locations where the protected effect is determined depends of the perimeter, the form of the protected area and agreement between the customer and supplier.

B.11.2.3 Procedure of measurement

a) The sample times should be determined based on ISO-14644-1:2015, A.4.4.

b) Begin the generation of particles in the lesser classified side of the air barrier assuring that the momentum of the challenge leaving the test apparatus does not overpower the air barrier.

c) Record particle concentration in the lesser classified area at each probe(s). A minimum of three 1-minute measurements should be taken.

NOTE A dilution device can be required when measuring the high concentration.

d) record the particle concentration in the protected area at each probe(s). A minimum of three 1-minute measurements should be taken.

B.11.2.4 Calculating the protection index

The protection index is calculated with Formula (B.16):

$$PI_X = -\log (C_X/C_{Ref}) \qquad \text{(B.16)}$$

where

C_{Ref} is the reference particle concentration, expressed in p/m^3, for particles ≥0,5 µm (challenge concentration) of the nearest reference particle counter, (guidance value: >5 × 10^6/m^3).

C_X is the average particle concentration at measuring point x, expressed in p/m^3, for particles ≥0,5 µm;

PI_X is the protection index;

B.11.3 Test reports

By agreement between the customer and supplier, the following information and data should be recorded as described in Clause 5:

a) designation of the type of each measuring apparatus used and its calibration status;

b) data collection technique;

c) measuring point locations;

d) occupancy state(s);

e) result of measurement.